

GENETIC SCREENING AND THE HANDLING OF HIGH-RISK GROUPS IN THE WORKPLACE

HEARINGS BEFORE THE SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT OF THE COMMITTEE ON SCIENCE AND TECHNOLOGY U.S. HOUSE OF REPRESENTATIVES NINETY-SEVENTH CONGRESS FIRST SESSION

OCTOBER 14, 15, 1981

[No. 53]

Printed for the use of the
Committee on Science and Technology



U.S. GOVERNMENT PRINTING OFFICE
WASHINGTON : 1982

88-583 O

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GENETIC SCREENING AND THE HANDLING OF HIGH-RISK GROUPS IN THE WORKPLACE

WEDNESDAY, OCTOBER 14, 1981

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT,
Washington, D.C.

The subcommittee met at 9 a.m., in room 2325, Rayburn House Office Building, Hon. Albert Gore, Jr. (chairman of the subcommittee) presiding.

Present: Representatives Gore, Walker, and Shamansky.

Mr. GORE. The subcommittee will come to order. I'd like to welcome all of you here this morning.

The increasing costs of making improvements in the workplace environment and the financial burdens posed by workers' compensation and similar statutes have provided many industries with a strong economic incentive to engage in preemployment screening. Such screening utilizes our increasing scientific knowledge of human variation in an effort to identify those portions of the potential workforce which are at highest risk. By selecting employees in a manner which minimizes the number of these so-called hypersusceptible workers, companies hope to decrease the incidence of occupational illness and thereby decrease the associated costs of compensation.

This morning, we begin a series of hearings which will explore the difficult issues raised by research into human variation and the application of such research to occupational settings. The subcommittee will review the methods by which high-risk groups are identified and the consequences that such classifications have for individual workers and for society at large. We will attempt to address a number of the broad scientific and policy questions:

First, how should we define high risk. Studies of asbestos workers by Irving Selikoff indicate that they are, as a group, five times as susceptible to lung cancer than other workers. They are clearly a high-risk group. Among asbestos workers, however, those who smoke are at still higher risk—perhaps up to 10 times that of their coworkers. By focusing on asbestos workers who smoke, however, do we tend to ignore the hazards faced by all who work with asbestos? Do we create a false sense of security among asbestos workers who do not smoke?

Second, how sensitive and how accurate are currently available screening techniques? Which techniques represent reliable predictors of risk? What protection should be available to job applicants who are labeled by such tests as susceptible? What protection

should be available to workers who fear loss of employment or transfer to a lower paying job?

Third, what do these tests measure? Do they attempt to identify some genetic attribute or will they reflect in older workers the effects of chronic exposure to industrial toxins?

Fourth, what types of new genetic screening techniques loom on the horizon? Which have been tried? What results have been obtained?

Fifth, how do we insure that screening will not be substituted for improvements in the workplace environment? Will plant managers view the removal of high-risk workers as a panacea for occupational exposure problems?

Finally, does the increasing use of workplace screening techniques shift the burden of occupational hazards from the employer to the employee? Instead of modifying the workplace so that it is safe for all employees, are we simply modifying the composition of the workplace to fit the existing environment? What policies should we make for the pool of high-risk employees who cannot find work? At what point does screening according to innate characteristics constitute invidious discrimination?

In addition to focusing on the broader issues, the subcommittee will focus on two specific illustrations of workplace screening: pre-employment back X-rays conducted by the railroad industry and job selection based on sex in the chemical industry.

The value of preemployment back X-rays has been a matter of some debate among occupational physicians. Their use has been based on the assumption that certain developmental abnormalities detectable with X-rays accurately predict an increased incidence of low-back injury. The high incidence of such injuries poses a serious health problem for employees and a significant financial burden for employers. This case provides an excellent illustration of both the incentives to screen workers and the serious ethical and legal issues which invariably arise from such programs.

The efforts of companies to select workers for high-risk jobs based on sex illustrates additional problems which workplace screening programs create. In this case, companies in the chemical industry have excluded fertile women from certain jobs based on the presence of reproductive hazards. The scientific basis for concluding that women are at risk is not disputed; however, the legitimacy of such screening has been questioned in the light of scientific evidence pointing toward the existence of reproductive hazards to men as well.

These issues are, of course, difficult ones to resolve. With that in mind, I want to make it clear that these hearings are not in any way designed to point an accusatory finger at any group; rather, we will be focusing on specific examples of workplace screening because of their value as illustrations of the types of problems which are arising with increasing frequency in widely varying contexts, and because of our anticipation that such practices will become much more commonplace in the future.

The ultimate concern of this subcommittee in this series of hearings is with genetic engineering, and the use of medical screening techniques to identify genetic variation in the population. It is the potential identification of genetic preferences and the selection of

workers on the basis of genetic criteria which stirs the most serious concerns. The cases which we have selected for review during these first 2 days of hearings can be seen as models for analysis for more sophisticated testing. It is to this advancing genetic technology that the subcommittee will turn in later hearings this fall.

I appreciate all of our witnesses coming today and tomorrow too. We will begin with a panel of three people: Dr. Ernest E. Dixon with Tabershaw Associates in Rockville; Dr. Hans Weill, professor of medicine at Tulane University; and Mr. Sheldon Samuels, health director for Industrial Union Department for the AFL-CIO. And we will start with you, Dr. Dixon.

At this point in the record, I would like to ask unanimous consent to include the opening statement of my colleague, Mr. Walker, who may wish to deliver it when he arrives. He's driving en route from Pennsylvania this morning and is going to be here in a short time.

[Opening statement of Congressman Robert S. Walker follows:]

OPENING STATEMENT OF CONGRESSMAN ROBERT S. WALKER

Mr. Chairman, the hearings we shall begin this morning are an attempt by this committee to clarify a number of troubling issues which now face our society. We are becoming increasingly aware that the blessings of modern technology are often mixed.

The more we learn about the potential effects of chemical, electrical, magnetic, and radiation upon the human system, the more we realize that there are new, and sometimes insidious dangers in both the workplace and within the home.

Research is making great strides in identifying these threats. As each new threat is identified we are attempting to develop an effective response.

Today we will be hearing about new techniques which may help to identify individuals who are predisposed to certain problems. The validity of these tests and techniques have been questioned in the past by various parties. We cannot, and will not make any determination as to their validity in these hearings. We will study the testimony to determine if the techniques show promise for future alleviation of similar problems through avoidance of hazardous situations for individuals who are particularly susceptible.

In the past there have been proposals that the Government should regulate screening of this type. It is my belief that such regulation is both unnecessary and undesirable on this particular issue. I think Thomas Jefferson was absolutely correct when he said, "That Government governs best which governs least."

Before we hear from our first witness today I would also like to add that there are both moral and ethical questions which are raised by the use of these techniques. While I have a predisposition against governmental regulation, I also realize that we in the Congress carry a heavy burden in our determinations of the proper governmental response to threats against the health and welfare of the American people. This has been an area of some controversy in the past. We hope that this hearing will either resolve that controversy, or else lead to new approaches to reduce the controversy in the future.

Mr. GORE. Without objection, we will also include the entire text of the prepared remarks of this panel of witnesses and I'd like to invite you to proceed, Dr. Dixon. Thank you for coming.

[The biographical sketch of Dr. Dixon follows:]

TABERSHAW OCCUPATIONAL MEDICINE ASSOCIATES, P.A.
TABERSHAW SERVICES, INC.

CURRICULUM VITAE

ERNEST M. DIXON, M.D.
Senior Occupational Health Physician

EDUCATION:

University of Virginia, M.D., 1947.
University of Cincinnati, Doctor of Science, 1957.

SPECIALTY STATUS:

Certified as a specialist in Occupational Medicine,
American Board of Preventive Medicine, 1960.
Fellow of the American College of Preventive Medicine,
1961.
Senior Surgeon (Lt. Col.), U.S. Public Health Service
Reserve (Inactive)

EXPERIENCE:

1981	Senior Occupational Health Physician, Tabershaw Occupational Medicine Associates, P.A.
1965-1981	Corporate Medical Director, Celanese Corporation, New York, N.Y.
1963-1965	Chief Medical Officer, American Telephone and Telegraph Company, New York, N.Y.
1962-1963	Headquarters Medical Director, Western Electric Company, New York, N.Y.
1958-1962	Director of Medical Services, American Cyanamid Company, Bound Brook, N.J.
1957-1958	Chief Physician, Cyanamid Research Laboratories, Stamford, Conn.
1956-1957	Plant Physician, American Cyanamid Company, Fortier Plant, New Orleans, La.
1954-1957	Fellow in Occupational Health, The Kettering Laboratory, University of Cincinnati. The third year of this Fellowship was devoted to in- plant, preceptorship training in various medical departments of the American Cyanamid Company.
1953-1954	U.S. Public Health Service. Internist of industrial toxicology research team.
1950-1953	Private practice - internal medicine, Roanoke, Va.
1949-1950	Lieutenant (j.g.), United States Naval Hospital, Portsmouth, Va. Officer-in-charge of cardiovascular unit of Internal Medicine Service.
1947-1949	Intern and resident, University of Virginia Hospital, Charlottesville, Va. (Internal Medicine and Pathology).

PROFESSIONAL SOCIETIES:

The Medical Society of the County of New York
 The Medical Society of the State of New York
 Fellow of the American Academy of Occupational
 Medicine (Director)
 Fellow of the Industrial Medical Association
 American Industrial Hygiene Association (Director)
 American Medical Association
 Fellow of the New York Academy of Medicine
 New York Academy of Sciences
 Fellow of the American College of Preventive Medicine
 Fellow of the American Public Health Association
 American Association for the Advancement of Science
 New York Medical Directors
 Ramazzini Society
 The Medical Executives (President)
 Member of the National Advisory Committee on
 Occupational Safety and Health

**STATEMENT OF ERNEST E. DIXON, TABERSHAW ASSOCIATES,
ROCKVILLE, MD.**

Dr. DIXON. Thank you.

I am Dr. Ernest M. Dixon, a private practitioner in the medical specialty of occupational medicine. I appear today at the invitation of the subcommittee to testify on medical and genetic screening programs in the workplace.

In recent years the value of health monitoring of workers has become recognized as being of increased importance. Many of the NIOSH recommendations and OSHA standards associated with substance exposures have specific recommendations for medical surveillance. These include specified tests which are uniquely characteristic of, or helpful in, establishing a diagnosis—and in providing an experiential baseline level in the worker prior to working with potentially hazardous materials. Also, where it is known that certain health conditions predispose to increased susceptibility—above that of normal individuals—to a given exposure, screening or testing to determine the presence or absence of the predisposing condition may be undertaken.

General health evaluation prior to exposure is of considerable importance. Since test results for individuals may vary over a wide range of normal values, knowing the baseline level of an individual may be of critical importance. Also, a departure from an individual's normal level, even though still in the normal range, may be of greater significance than a single value classified as abnormal. For example, a person who normally has a high red blood count may show a change even though he's in the normal range at a low level in the range of normal and that would be significant, whereas the single reading itself would not be.

General health evaluations, notwithstanding the benefits of special screening procedures, remains the method of choice. It should include a medical history, physical examination, laboratory and other tests, such as chest X-ray, pulmonary function, audiogram, electrocardiogram, et cetera, as may be indicated. Such assessments can establish a general baseline and create a health profile that provides the fundamental basis for worker selection and place-

ment to avoid undue risks. To this basic health evaluation should be added any pathognomonic or other specialized tests which may be appropriate for the given exposure. Most of these examination and testing measures are conventional clinical procedures and, as such, are well established as to accuracy, standardization, ranges, et cetera. Unfortunately, however, despite substantial new developments in clinical laboratory science, there are all too few substances for which there are specific tests.

Of special interest and concern is the relatively new area of screening for genetic abnormalities. This is an area which is rapidly developing and is the subject of extensive research. Much is known about the genetic basis and nature of many disorders and there is a moderate amount of information on genetic abnormalities in test systems induced by toxic agents. The use of screening tests to predetermined genetically increased susceptibility to potentially harmful physical or toxic agents in humans is, however, extremely limited at present. I can list only four or five for which there is an established basis, and to summarize them hurriedly, one is the serum antitrypsin tests for respiratory irritants; and the glucose-6-phosphate dehydrogenase test which can detect antimalarial and other drugs and potentially hemolytic chemicals; the hemoglobin S in sickle cell anemia which can produce problems with deficient oxygen at high altitude and possible or probable nitro and amino chemical compounds; and the whole allergic reactions field due to allergens which vary all the way from pollens to chemicals such as toluene diisocyanate.

In addition to these well established procedures, which are determined by clinical means—and I want to emphasize clinical means—there are a group of newer short-term genetic monitoring tests for chromosomal aberrations. These may determine mutations, which are heritable changes in cells, or genetic damage, which may be either reparable or lethal to the cell instead of inducing heritable change. Among the testing methods are cytogenetics, sister chromatid exchange, body fluid analysis, testing of sperm cells and detection of somatic cell variants. Most of the cytogenetic studies in industry have been recent—during the past decade—and are directed at assessing the degree of chromosomal aberration occurring in cells—generally cultured lymphocytes—in individuals subsequent to work exposure to chemicals such as benzene, vinyl chloride monomer, and epichlorhydrin.

Without going into any of the specifics of testing techniques and difficulties therein, it is fair to say that all of the studies done thus far are seriously flawed due to the complexity and inadequate control of the many variables, improper experimental design, incorrect epidemiologic interpretation, inadequate validation, lack of standardization, nonreproducibility and genetically irrelevant end points. In some instances studies have been undertaken to develop a baseline of the frequency of aberrations in nonexposed groups. However, I know of no instance in which a reliable conclusion has resulted.

In view of all the confounding difficulties and inherent uncertainties, at least thus far in their development, such genetic tests must be relegated to the category of the experimental, that is, as research tools only. None of these short-term tests have achieved

the status of clinical tests—and unless or until such does occur they cannot be assigned any interpretive or predictive value. It is a testing modality which warrants further research—and I would urge it—but it must be limited to research status only until the many problems have been resolved and reasonable reliability has been achieved. Genetic testing has had extremely limited use in industry thus far and has been essentially limited to research study only, to my knowledge.

Clinical health surveillance or medical screening, on the other hand, has a long-established basis of scientific legitimacy and validity. It is used quite extensively in industry today and is especially prevalent in industries having obvious potential hazards to health. Its utility, however, is wholly contingent upon examinations being tailored by experts in occupational medicine to monitor selectively and to interpret properly the results. Only through such surveillance programs correlated with work histories and exposure data is it possible to assure worker health. This includes consideration of future expected exposure and work information to aid in proper placement and past data to assess for the presence or absence of adverse health effects from past work. It requires physicians knowledgeable in the specialty of occupational health to tailor programs appropriately and to interpret the results. All too often, individuals who are experts in a given test technology or physicians lacking occupational health skills are called upon to render such judgments. The dilemmas that can result when unqualified individuals make the decisions are evident in some regulatory standards and in the public decisionmaking arenas. Many organizations, with do-good intent, have pressed for or against a special measure without any depth of understanding of the complex issues involved and have unwisely influenced policy decisions. Similarly, those with a mission and dedication in pursuit of promoting a method or procedure may be so zealous and persuasive as to influence decisionmakers to make wrong choices.

A conscientiously administered medical surveillance program is the keystone to assuring the health of workers. A properly implemented program to assess general health and to examine specifically the organ system functions at risk is the only means available to assure that individuals can safely undertake potentially hazardous work or that they have not suffered any adverse health effects. Despite all preventive and precautionary measures that can be undertaken, it is only by demonstrating no adverse health effects in workers that assurance of safety can be established. Conversely, detection of adverse effects, hopefully at as early a time as possible, is a signal for taking more effective precautionary and remedial actions. Confidential, high-quality medical examination programs correlated with work and exposure history by means of a systems approach can now provide a highly effective means of protecting the individual and groups of workers. The data base systems approach to health surveillance today offers a whole new vista of improved technologic capability. As new testing methods that can be helpful are developed they should be added to the armamentarium of medical surveillance technology, but only as they become fully validated.

Based on the suggested areas of comment and special questions posed for this inquiry, it is evident that the committee is searching to determine which methods and procedures are proper and useful, how to avoid possible abuses and the efficacy of protection that medical surveillance can provide.

In my earlier comments, I have attempted to describe an overview of medical and genetic testing as it exists today. My view of genetic testing is that it is in its infancy and is generally inappropriate today, except as a research tool. I favor its development and proper use when it becomes established because we need every technologic advance possible to assist us in attaining enhanced predictive and diagnostic capability. I consider conventional medical testing to be highly effective and appropriate. The new occupational health management systems which include medical surveillance programs can be highly effective in the hands of and when directed by skilled occupational health specialists.

If an individual is discovered to have a genetic deficit or other medical abnormality which would put him at a risk greater than normal individuals, added protective measures or precluding him from exposure to the special hazard is obviously the reasonable approach. Concern for an individual who is known to be hypersusceptible to adverse effects from any agent requires protection from exposure beyond that which normal individuals may tolerate readily. Control of the degree of exposure should be the primary objective, if it is possible and feasible to achieve, but an individual should not be assigned to work if it is not possible to assure his own safety or if it would jeopardize others. Any approach to solving problems of this nature should be individualized and strictly practical and not by broad categorical or policy solutions which could be discriminatory. Companies with which I am familiar generally take the highly individualized approach within the limits of knowledge and preclude broad discriminatory policies and actions as much as possible. This mandates that examinations be selectively designed with knowledge of the job requirements, utilize tests with established merit, and with interpretation of the results by experts and professionals who have sufficient information to sustain their conclusions.

Among the legitimate issues to be accomplished by testing are determinations regarding: physical capacity to do the job without harm to self, others, or property; potential harm to the individual worker and his offspring; productivity; and liability.

It should be kept in mind that medical surveillance occurs in two principal categories:

One, initial or preplacement examinations which are done to establish a baseline for future reference and to determine if the individual can physically perform the intended work and whether or not there is any health condition which might require special precautionary care or job placement consideration.

Two, periodic examinations after engaging in work to assure that no adverse health effects are developing or, if so, that they are detected sufficiently early to permit remedial action and preclude lasting ill consequences.

In my judgment, the benefits in worker health protection afforded by properly and fairly conducted health surveillance far

outweighs any risk that discriminatory decisions might pose. However, there are ethical and social dilemmas to be addressed. When it comes to a health problem of an individual posing a hazard to other individuals or property, there can never be a decision to accept the latter. When the deliberation involves only a hazard to the individual, the decision is less easy or clear-cut. Even if we exclude employer liability as an issue, the moral aspects cannot be denied or easily resolved.

Is the harm of not being able to work at a specific task because of a health problem worse than being allowed to do the work and assuming the consequences of an adverse health effect? Even if we could quantify the severity—discomfort, mild or severe disability, death—it, offers little help in answering the question. The physician feels compelled to urge avoidance of any risk to health. There is a parallel in the case of the physician insisting on surgery for appendicitis but the patient refusing; should the physician or the State force the individual to undergo surgery?

In industry, the role of the physician is primarily advisory to management but his recommendation should be given great weight. Where there are other issues of concern to management, such as productivity, management must make the decision. In my judgment, in instances of hazard to self or others, the knowledgeable physician's determination should be accepted. But who is to decide whether or not an individual can work? This is an issue that is never decided easily.

Certainly both sides should be informed of the physician's recommendations. But ultimately, who decides? If a dispute arises, it would be best for a judgment to be made by a panel or board of review of neutral specialists in occupational medicine. Physicians in other medical specialties lack the perspective and technical skill to adequately make the "whole worker" assessment. Unqualified people too often are the arbiters. By utilizing available expertise, the best knowledge and judgment can be brought to bear on these problems effectively. I do not believe that workers should be permitted to assume the risks of bodily harm just because they are shielded from the risks of financial loss.

Limiting workplace exposures to the greatest extent feasible is always the first preference for eliminating or minimizing health risks. In some instances of hypersusceptibility, the degree of control that would have to be achieved may be unattainable by available engineering measures or be prohibitively costly. If the costs are excessive and impinge seriously on the financial health of the enterprise, the benefit to a few could be outweighed by the harm to the majority of workers and it might be better to place hypersusceptible workers elsewhere. Also, if the nature of the hazard is potentially severe for the unusually susceptible worker, it would not be in his best interest to permit him to work in such circumstances.

I have tried to cover briefly the general considerations on medical and genetic screening, testing and surveillance. In my judgment, proper programs of testing, in which qualified specialists in occupational health tailor programs broadly enough to assess general health levels and to specifically measure the function of organ systems at risk, constitute the most effective measures for health

protection of workers. Knowledgeable and ethical professional conduct is, in my judgment, sufficient constraint against "invidious discrimination on the basis of some physical trait."

[The prepared statement of Dr. Dixon follows:]

PREPARED STATEMENT OF ERNEST M. DIXON, M.D., Sc.D.

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Of special interest and concern is the relatively new area of screening for genetic abnormalities. This is an area which is rapidly developing and is the subject of extensive research. Much is known about the genetic basis and nature of many disorders and there is a moderate amount of information on genetic abnormalities in test systems induced by toxic agents. The use of screening tests to predetermined genetically increased susceptibility to potentially harmful physical or toxic agents in humans in, however, extremely limited at present. Among those for which there is an established basis are:

Category	Example	Physical or toxic agent
Missing or deficiency of essential substance.	Serum antitrypsin (SAT)	Respiratory irritants.
Absence of deficiency of enzyme	Glucose-6-phosphate dehydrogenase (G6PD).	Antimalarial and other drugs; potentially hemolytic chemicals.
Presence of abnormal substances (protein).	Hemoglobin S in sickle cell anemia	Deficient oxygen at high altitude; nitro and amino chemical compounds.
Abnormal antibody production.....	Allergic reactions	Allergens—from pollens to chemicals such as toluene diisocyanate.

In addition to these well established procedures, which are determined by clinical means, there are a group of newer short-term genetic monitoring tests for chromosomal aberrations. These may determine mutations, which are heritable changes in cells, or genetic damage, which may be either repairable or lethal to the cell instead of inducing heritable change. Among the testing methods are cytogenetics, sister chromatid exchange, body fluid analysis, testing of sperm cells and detection of somatic cell variants. Most of the cytogenetic studies in industry have been recent (during the past decade) and are directed at assessing the degree of chromosomal

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In my earlier comments, I have attempted to describe an overview of medical and genetic testing as it exists today. My view of genetic testing is that it is in its infancy and is generally inappropriate today, except as a research tool. I favor its development and proper use when it becomes established, because we need every technologic advance possible to assist us in attaining enhanced predictive and diagnostic capability. I consider conventional medical testing to be highly effective and appropriate. The new occupational health management systems which include

medical surveillance programs can be highly effective in the hands of and when directed by skilled occupational health specialists.

If an individual is discovered to have a genetic deficit or other medical abnormality which would put him at a risk greater than "normal" individuals, added protective measures or precluding him from exposure to the special hazard is obviously the reasonable approach. Concern for an individual who is known to be hypersusceptible to adverse effects from any agent requires protection from exposure beyond that which normal individuals may tolerate readily. Control of the degree of exposure should be the primary objective, if it is possible and feasible to achieve, but an individual should not be assigned to work if it is not possible to assure his own safety or if it would jeopardize others. Any approach to solving problems of this nature should be individualized and strictly practical and not by broad categorical or policy solutions which could be discriminatory. Companies with which I am familiar generally take the highly individualized approach within the limits of knowledge and preclude broad discriminatory policies and actions as much as possible. This mandates that examinations be selectively designed with knowledge of the job requirements, utilize tests with established merit and with interpretation of the results by experts and professionals who have sufficient information to sustain their conclusions.

Among the legitimate issues to be accomplished by testing are determinations regarding: Physical capacity to do the job without harm to self, others or property; potential harm to the individual worker and his offspring; productivity; and liability.

It should be kept in mind that medical surveillance occurs in two principal categories:

(1) Initial or preplacement examinations—to establish a baseline for future reference and to determine if the individual can physically perform the intended work and whether or not there is any health condition which might require special precautionary care or job placement consideration.

(2) Periodic examinations after engaging in work to assure that no adverse health effects are developing or, if so, that they are detected sufficiently early to permit remedial action and preclude lasting ill consequences.

In my judgment (and that of many experts in the field), the benefits in worker health protection afforded by properly and fairly conducted health surveillance far outweigh any risk that discriminatory decisions might pose. However, there are ethical and social dilemmas to be addressed. When it comes to a health problem of an individual posing a hazard to other individuals or property, there can never be a decision to accept the latter. When the deliberation involves only a hazard to the individual, the decision is less easy or clear cut. Even if we exclude employer liability as an issue, the moral aspects cannot be denied or easily resolved.

Is the harm of not being able to work at a specific task because of a health problem worse than being allowed to do the work and assuming the consequences of an adverse health effect? Even if we could quantify the severity (discomfort, mild or severe disability, death), it offers little help in answering the question. The physician feels compelled to urge avoidance of any risk to health. There is a parallel in the case of the physician insisting on surgery for appendicitis but the patient refusing; should the physician or the state force the individual to undergo surgery?

In industry, the role of the physician is primarily advisory to management but his recommendation should be given great weight. Where there are other issues of concern to management, such as productivity, management must make the decision. In my judgment, in instances of hazard to self or others, the knowledgeable physician's determination should be accepted. But who is to decide whether or not an individual can work? This is an issue that is never decided easily.

Certainly both sides should be informed of the physician's recommendations. But ultimately, who decides? If a dispute arises, it would be best for a judgment to be made by a panel or board of review of neutral specialists in occupational medicine. Physicians in other medical specialties lack the perspective and technical skill to adequately make the "whole worker" assessment. Unqualified people too often are the arbiters. By utilizing available expertise, the best knowledge and judgment can be brought to bear on these problems effectively. I do not believe that workers should be permitted to assume the risks of bodily harm just because they are shielded from the risks of financial loss.

Limiting workplace exposures to the greatest extent feasible is always the first preference for eliminating or minimizing health risks. In some instances of hypersusceptibility, the degree of control that would have to be achieved may be unattainable by available engineering measures or be prohibitively costly. If the costs are excessive and impinge seriously on the financial health of the enterprise, the benefit to a few could be outweighed by the harm to the majority of workers and it might

be better to place hypersusceptible workers elsewhere. Also, if the nature of the hazard is potentially severe for the unusually susceptible worker, it would not be in his best interest to permit him to work in such circumstances.

I have tried to cover briefly the general considerations on medical and genetic screening, testing and surveillance. In my judgment, proper programs of testing, in which qualified specialists in occupational health tailor programs broadly enough to assess general health levels and to specifically measure the function of organ systems at risk, constitute the most effective measures for health protection of workers. Knowledgeable and ethical professional conduct is, in my judgment, sufficient constraint against "invidious discrimination on the basis of some physical trait."

Medical Surveillance in Industry

Ernest M. Dixon, M.D., Sc.D.

At first the subject of biologic monitoring in industry presented no difficulty since I am familiar with the practice of performing tests on humans to assess exposure to potentially harmful agents, or, more correctly stated, to assure that excessive absorption or ill effects are not occurring as a consequence to that exposure.

To my chagrin, two perplexing questions developed in my initial efforts to plan the presentation: (1) The appropriateness of the term biologic monitoring itself; (2) The growing sense of an OSHA attitude of disfavor toward testing the man—with reliance on environmental testing being the only acceptable means of assuring worker safety.

My concern regarding the term developed when quite by chance one of our managers asked me what biologic monitoring meant—would we have to set up animal colonies in the workplace to determine any adverse effects? Were we going back to using "canaries in the mines?" During the next several days I asked approximately two dozen knowledgeable lay persons in management positions in companies manufacturing chemicals and related products what they thought was meant by the term biologic monitoring as used in relation to OSHA. Almost all were unaware of its real meaning. Most thought it had something to do with animal tests but they had no clear conception. After I clarified the term, each individual volunteered that this term should be changed. The most interesting alternative suggested by one of them was "precautionary human (or medical) testing."

In view of my own uncertainties and the reactions just cited, I undertook lengthy verbal discussions with ten, and I wrote to 15 additional leading experts in our field. They included representatives of the academic, governmental, and industrial sectors. Thirteen of those 15 responded with lengthy and thoughtful written comments and one responded at length verbally. The request stated that, "specifically, I would welcome your comments on:

1. Appropriateness of the term itself and any suggestions for an alternative term that would more appropriately indicate human clinical-type tests for assessing the adequacy of exposure controls and/or other aspects of human monitoring.

2. Your general views on the pros and cons of the concept of biologic monitoring as a scientifically valid technique in a preventive occupational health program—as to its acceptability under OSHA and otherwise.

3. Specific examples in which "biologic monitoring" is uniquely the only currently acceptable method for assessing exposure and, conversely, examples in which "biologic monitoring" cannot be achieved currently.

4. Any other considerations which you might wish to offer.

Among the responses, reaction to the term itself was quite varied with approximately even division among three categories: (1) satisfied with the term, (2) no strong feeling, and (3) opposition to the term. Among those satisfied with or indicating no strong feeling about the term, there was a general indication that the term was sufficiently entrenched that to change it would be difficult. One participant resigned to the term replied, "as so often, it seems to be an inexact shorthand that most of us accept because of its practicality." There was some very strong opposition to the term with comments to the effect that the word biologic more generically connotes matters relevant to animals and plants—that humans want to be medically tested rather than biologically monitored. Among the alternatives suggested are human, medical, health, clinical, employee, physiological, or personnel monitoring, biometry, periodic biomedical evaluations, biologic thresholds, bio-functional or physiological testing, medical surveillance and medical testing. After extensively reviewing the subject, I concluded that the term biologic monitoring is totally confusing to lay persons. It is professionally inexact, inappropriate and it lacks proper indication of scientific, medical and human concern. Accordingly, I fall into the group strongly opposing the term. The alternative term which I have chosen, wish to promote, and will use throughout the remainder of this presentation is medical surveillance. To me this sets a proper perspective requiring professional medical purview, close supervision and astute clinical judgement—a framework within which it must be conducted if it is to be achieved with the significance that is essential. Medical surveillance is sufficiently inclusive a term to cover all types of medical observations and testing done at present or that may be developed in the future—including all physiologic measurements of functions, performance, chemical and enzyme levels or alterations, and indirect measurements. This concept is not confined to just the conventional analyses of blood and urine but embraces every human parameter capable of being medically assessed.

With respect to the pros and cons of medical surveillance being a scientifically valid technique in preventive occupational health programs, there was complete unanimity among all participants. They agreed that it is absolutely essential and that it is ultimately the only way of measuring what the actual exposure of a worker has been and determining the

Dr. Dixon is Corporate Medical Director, Celanese Corp., 522 Fifth Ave., New York, N.Y. 10016.

Presented at 58th Annual Meeting of the Industrial Medical Association at the American Industrial Health Conference, Denver, Col., April 16-19, 1973.

presence or absence of any adverse effects. There was a uniformly similar strong aversion to any intent under OSHA for medical surveillance to be rejected or in anyway downgraded or disallowed in instances where it is known to be the most reliable means of assuring worker protection. As might be expected, there was great emphasis that in no instance should we condone its being used *per se* as the device or instrument for assessing the existence of a hazard or measuring its magnitude. Indeed, such an abuse of the individual would be inhuman and intolerable. In all instances, therefore, the intent and object is to achieve a final check upon the adequacy of the program designed to prevent harmful exposure. To eliminate medical surveillance, for whatever reasons of advantage that it might afford OSHA, would be a tragic error leading to measuring only the "health of the air" or working environment with disregard for protecting the health of the individual. One authority commented, "the intent of the act is not protection of the health of the air; it is protection of the health of the individual . . . the measurement should be of the health of the workers and not (just) of the health of the air." This is equally true of any work environment influence of a potentially harmful nature.

In no way do I wish to imply or even suggest that industrial hygiene analytical and related functions are in any manner less important than we have always considered them. They are, in fact, the cornerstone and basic foundation of our planning to prevent ill effects from toxic and other harmful effects in the work environment. In my judgement, purely industrial hygiene measures have contributed more than have purely medical activities in reducing the effects of toxic substances, radiation and other forms of energy, noise, heat and cold stress, excessive work effort and many other potentially harmful influences on our working people. Nevertheless, the most diligently applied industrial hygiene programs are inherently beset with the possibility of failure in that they cannot possibly provide absolute assurance that the worker is safe. Even if TLV's are observed scrupulously, there is no assurance that the individual adheres to practices that preclude excessive exposure. Breaks in techniques of safe working practices, such as unplanned skin exposure or handling contaminants just prior to meal time or smoking can totally invalidate the most exactingly careful precautionary plans.

Newer methods utilizing personal sampling monitors which continuously measure the individual's actual environmental exposure may help greatly, but they do not take into account transdermal absorption or any failure based upon sudden, brief exposures at high levels beyond the capability of the instrument to cope. If fail-safe, continuous personal monitoring equipment capable of handling all levels of exposure with reliability are developed, then, except for dermal and oral exposure possibilities, medical surveillance might no longer be needed for routine industrial health control. However, as Stokinger¹ has indicated, air-borne concentrations as an index of exposure are also unreliable in situations of mixed exposures with metabolic interaction, individual peculiarities of work habits leading to abnormal intake and additive exposure off the job. By reflecting all of the possible variables, medical surveillance can provide both an index of exposure and an index of response. Accordingly, only medical surveillance techniques, if available for the specific exposure, could ascertain that the individual worker is completely safe and has incurred no adverse effects.

The complexity of health evaluation is a very real problem and is growing with the passing of time. Simple tests and observations of the past years have been supplanted by vastly more complicated and technically involved methods. The report of the "National Commission on State Workmen's Compensation Laws" states:

Technological advances have produced unfamiliar and often indeterminable physical and toxic hazards. Occupational diseases associated with prolonged exposures to unsuspected agents or to fortuitous combinations of stresses have undermined the usefulness of the 'accident' concept. While advances in medical knowledge have facilitated the treatment of many injuries and diseases, they have also enlarged the list of diseases that may be work-related. Simple cause-effect concepts of the past have yielded to an appreciation of the many interacting forces that may result in impairment or death. In addition to genetic, environmental, cultural, and psychological influences, physicians must consider predisposing, precipitating, aggravating, and perpetuating factors in disease. Etiologic analysis, estimates of the relationship to work, and evaluation of the extent of impairment have become accordingly complex for many illnesses.

Thus, it is readily evident that our medical task is difficult. A basic predicament in occupation medicine is a limited technological capability for medical surveillance analytical methods. When one considers the large number of chemical substances in use in contrast to the few for which we have established and confirmed ability to assess absorption reliably, the magnitude of the problem is readily apparent. Although I have made no attempt to cite all of the substances which are fully recognized as having valid medical surveillance indicators of the degree of exposure or bodily intake, it is appropriate to mention some well known examples: heavy metals such as lead, cadmium, chromium and nickel, the various cholinesterase inhibitors, carbon monoxide, methemoglobin formers such as aniline and nitrobenzene, toluene, benzene and other hydrocarbon solvents.

The control of lead poisoning represents one of the great classics in the history of occupational medicine. In conjunction with good work practices, industrial hygiene control measures and, as the ultimate safeguard, the medical surveillance techniques of accurate analyses of urine and blood lead levels of workers, it has become possible for men to safely engage in all types of work utilizing lead.

Another interesting point with respect to lead is that in the new NIOSH criteria for a recommended standard entitled "Occupational Exposure to Inorganic Lead", there is the specific requirement for medical surveillance (biologic and medical monitoring) of all workers subject to exposure to inorganic lead. The standard sets forth specific procedures for sampling and analysis of blood or urine. It also prescribes the frequency of testing and requirements for environmental sampling and analysis. This is a major step in the right direction for OSHA and represents a reaffirmation of the essential need for testing the man and the inescapable re-introduction of utilizing skilled professional judgement. I hope this is the beginning of the end of the "numbers-in-the-air" game in which TLV's and other standards are arbitrary rigid limits—rather than guidelines subject to professional interpretation. Lord Robens Committee Report on the British System points out its chaos with voluminous provisions and standards for achieving safe and healthy working conditions.² It is obvious from this report and

more recent comments from NIOSH that inevitably the only system which can succeed is one which prescribes good work practices based on known standards and guidelines plus appropriate medical surveillance—with professional judgement being the most meaningful ingredient necessary for success.

Although it is true that we do not have anything like enough reliable human indicators available to meet our current medical surveillance needs, a strengthened research program utilizing the fantastic array of new analytical technology could almost certainly devise means for measuring most of the physiological, functional or chemical alterations possibly created by work environment hazards. Additionally, newer technology being developed will soon permit us to accomplish many things that are impossible today. It is in this area that I believe our greatest emphasis should be placed in the immediate future. I hope such studies will eventually resolve areas in which medical surveillance is now totally unsuccessful, such as in human testing to assure total absence of adverse effects from exposure to carcinogens. However, many recent innovations offer great promise. The work of Stewart³ in developing breath analysis techniques which are consistent with blood levels and correlate with atmospheric exposure levels represents a great advance. His human studies have demonstrated another important aspect of medical surveillance—the finding of an otherwise unexpected abnormality—an increase in blood carbon monoxide in instances of exposure to one of the hydrocarbon solvents. A few of the newer developments that appear to offer considerable promise include: atomic absorption spectrometry and other complex means for analyzing finger nails, skin, hair, and other tissues for signs of toxicity; electroneuromyographic and other neurophysiologic methods for studying insidious effects of neurotoxic agents; many developments in enzymology; lysosomal changes and subcellular (mitochondrial) metabolic changes; chromosomal aberrations and circulating antibodies to agents in exposed persons. Newer procedures in prospective epidemiologic study of industrial populations holds forth great promise. The unique contributions of labor union records and cooperation in both retrospective and ongoing epidemiologic investigations have been clearly demonstrated by Selikoff, Hammond^{4,5} and others.

All of these and the coming generations of technologic developments should offer a remarkable opportunity for medical surveillance to become the ultimate in worker protection. I am convinced that medical surveillance alone can provide this ultimate degree of safety. One of my correspondents stated that it provides the only means of having an integrated approach for determining interaction of a potentially

hazardous agent with all of the variable characteristics of the individual such as his respiratory rate, size, metabolic pattern, genetic constitution, personal habits, multiple factor etiology, and other aspects of variability of response. In other words, the real measure of hazard to the worker is what is absorbed into his system and the physiologic response which this engenders. Inevitably this is related to a dose/effect relationship—a concept which we must staunchly support and promote in contrast to the zero tolerance outlook for which there is no physiologic justification.

It is imperative to mention the critically important necessity for developing suitable criteria for all new advances in medical surveillance capability. Without that, such testing would be meaningless and misleading.

In conclusion, I wish to emphasize my belief in the success of the historically balanced type of hazard control program consisting of industrial hygiene engineering methods to preclude improper exposure, industrial hygiene surveillance to determine adequacy of the control measures and medical surveillance as the ultimate measure to assure that the individual worker's health is not compromised. Expert professional judgement is the inherently essential ingredient. In my personal judgement, the term medical surveillance is superior to biologic monitoring and should be adopted. Finally, there is a great need for vastly expanded experimental facilities for extensive research on medical surveillance methods—since there is no really better way of measuring man's exposure and its effects.

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Although many individuals contributed to this paper, I especially acknowledge with appreciation the thoughtful help of Drs. M. Bundy, B. D. Dorman, R. M. Clyne, R. E. Eckardt, H. H. Gold, H. F. Howe, W. H. Jones, M. M. Kay, N. Nelson, N. I. Roberts, I. H. Wolfson, Messrs. E. J. Christofano, R. C. Wands and Mr. J. A. Tins, of Celanese, for editorial and other invaluable help.

HEALTH SURVEILLANCE IN INDUSTRY

Ernest M. Dixon, M.D., Sc.D.

Several years ago at an American Occupational Medical Association meeting, I presented a paper entitled "Medical Surveillance in Industry." At that time I thought I knew most of the answers; now I am less sure—but also I am certain that no one else knows all the answers. However, having long been concerned and having given considerable thought to this subject, I envision my role on this program, at least in part, as being somewhat the devil's advocate.

I think of health surveillance, especially when we currently view it to be one of the means of assisting in the protection of the health of workers and in meeting compliance requirements of the Occupational Safety and Health Act, as being awesomely complex, limited in its capacity to accomplish what is expected and logistically difficult. In part this is due to extreme problems with our entire system of national health care delivery, and I find myself deeply troubled and concerned with the developments which I have seen of late. Hence, it is my intent in this presentation to share with you some thoughts that are perhaps non-traditional and some differing perspectives.

This being our Bicentennial Year, I wish to recall two quotations appropriate to these deliberations:

In 1782, six years after the Declaration of Independence, Jean de Crevecoeur stated: "What then is the American, this new man? He is an American who leaving behind him all his ancient prejudices and manners, receives new ones from the new mode of life he has embraced, the new government he obeys, and the new rank he holds. The American is a new man, who acts upon new principles. He must, therefore, entertain new ideas, and form new opinions . . ."

And in 1787, just five years later, that early and eminent physician Benjamin Rush

wrote: "The American war is over. But this is far from being the case with the American Revolution. On the contrary, nothing but the first act of the great drama is closed. It remains yet to establish and perfect our new forms of government, and to prepare the principles, morals and manners of our citizens for these forms of government after they are established and brought to perfection."

What I'm driving at is that much of our traditional approach is of reduced relevance today; that innovation and new methods are desperately needed; and that the regulatory process remains disturbingly imperfect. It is, therefore, my purpose to review some of the problems and to allude to some possible solutions.

An analysis of the objectives of health surveillance requires consideration of some of the problems and inherent myths with which we are faced. As each newly proposed standard for a given chemical exposure issues, it has its unique specifications and language of health surveillance requirements for that substance alone. In the ideal circumstance such might be appropriate; but in the "real world" sense, this is very unsatisfactory and an imminent problem for a variety of reasons, prominent among which are the following:

Multiple Exposures It is rare for workers to be potentially exposed to a single substance only. Although such may occur at a given moment, over a period of time (days, weeks, or months), the probability of multiple exposures exists in most instances. Perhaps it was otherwise in times past—but certainly not now. Here we encounter the first stricture in the application of scientific principles and methods: when we know that health surveillance presently is incapable in all but rare instances of measuring any impact in the one-cause/one-effect relationship between an agent and reaction to it, how can we expect to realistically assess the multiple-cause/perhaps-more-than-one-effect condition? The application of Koch's postulates would be truly strained.

Multiple Effects of Individual Exposures There are many examples of vary-

ing effects from individual exposures to hazardous agents just as there are varying responses to naturally occurring diseases. Variations of response include the categories of acute versus chronic, localized versus disseminated, the reactions in various organ systems, and the impact in healthy versus unhealthy, young versus old, male versus female, and so forth. Good examples are the great imitators, lues and tuberculosis, which present greatly differing manifestations under differing circumstances.

Interaction of Occupational and Non-occupational Factors The range of variability in human response is dramatic. In determining the interaction of a potentially hazardous agent, one must consider all of the variable characteristics of the individual such as his respiratory rate, size, metabolic pattern, genetic constitution, personal habits, multiple factor etiology, and other aspects of variability of response. In other words, the real measure of hazard to the individual is what is absorbed into his system and the physiologic response which this engenders. Inevitably this brings into play a dose/effect relationship—a concept which we must staunchly support and promote in contrast to an empirical zero tolerance outlook for which there is no physiologic justification.

Complexity of Health Evaluation This is a very real problem and is growing with the passing of time. Simple tests and observations of the past years have been supplanted by vastly more complicated and technically involved methods. The Report of the National Commission on State Workmen's Compensation laws states: "Technological advances have produced unfamiliar and often indeterminable physical and toxic hazards. Occupational diseases associated with prolonged exposures to unsuspected agents or to fortuitous combinations of stresses have undermined the usefulness of the 'accident' concept. While advances in medical knowledge have facilitated the treatment of many injuries and diseases, they have also enlarged the list of diseases that may be work-related. Simple cause/effect concepts of the past have yielded to an ap-

preciation of the many interacting forces that may result in impairment or death. In addition to genetic, environmental, cultural, and psychological influences, physicians must consider predisposing, precipitating, aggravating and perpetuating factors in disease. Etiologic analysis, estimates of the relationship to work, and evaluation of the extent of impairment have become accordingly complex for many illnesses."

Thus, it is readily evident that our medical task is difficult. A basic predicament in occupational medicine is a limited technological capability for health surveillance analytical methods. When one considers the large number of chemical substances in use, in contrast to the few for which we have established and confirmed ability to assess absorption and effect reliably, the magnitude of the problem is readily apparent.

Several additional matters of great concern are our actual practices and standards for and inter-relationships between the following:

Health Surveillance First, I would issue a plea for universally adopting the term health surveillance, in place of medical surveillance, for all clinical and other measurements of human functions made on industrial workers. Since preparing this presentation, I have had access to Doctor Key's introductory comments. His statement concerning the origin of the term "biologic monitoring" has substantially influenced my thinking. He said, "I should point out that the term 'biologic monitoring' originated with the industrial hygienists and is indicative of their ability and intention of carrying out certain 'health monitoring' procedures—limiting factors being cooperation of the worker and ability to get blood, urine and breath samples."

The primary function of all of these measurements is to keep a vigil on the health of the workers. It should be a multi-disciplinary approach designed to protect the health of the workers and one designed to be positive—aimed at prevention, not treat-

ment. Workers are people and must be treated in the most humane way possible—not as subjects of a scientific study—and for this reason, the term 'biologic monitoring' is not appropriate and too limiting.

I am troubled by the emergence of all kinds of new surveillance schemes and differing requirements under new standards. I certainly agree to the importance of allowing judgment and not circumscribing initiative, but lack of any uniformity will create a nightmarish set of problems and utter chaos in any effort to assess the value of surveillance. This is especially true where there are multiple exposures with differing medical requirements. In the latter, differing exposures occurring sequentially over a period of time might require numerous separate examinations as well as new tests relating to each new exposure. Administration within the industry or industries for whom the individual worked would be extraordinarily complex, cumbersome, and difficult to achieve. The physician or physicians charged with the surveillance responsibility would find the task confusing, troublesome, and difficult to coordinate; this is especially true for private practitioners to whom the bulk of the job would fall; indeed, we have already encountered physicians who have long provided good services to industry refusing to undertake surveillance because of its vagarious and capricious requisites. In addition, numerous physicians have indicated reluctance or unwillingness to attest that a worker has or has not encountered adverse effects from exposures, may or may not be physically fit to undertake working with specific agents, and may or may not be physically able to use protective devices, for example, respiratory equipment.

For these and many other reasons, it has long been apparent to me that the only reasonable answer is the adoption of a uniform basic core health surveillance scheme where surveillance is deemed essential. This would consist of a standardized medical history, physical examination, and clinical tests such as chest X-ray, pulmonary function, urinalysis, hematology, and blood chemistry tests. To that would be added, as set forth in the standard issued for a given

exposure, any unique or particular test or tests, if any, that would be specifically helpful or diagnostic for that substance. Thus, there would be a basic procedure common to all surveillance requirements—with the addition of other observations only when such is markedly indicated. The adoption of this plan would result in:

- a. Simplification of surveillance for all concerned with avoidance of duplications and redundancies.
- b. Greater ease in administration—especially for physicians.
- c. Improved quality of examinations with attendant greater probability of attaining the intended objectives.
- d. Facilitating comparative study—between different locations, companies, and so forth, and long-term retrospective or other epidemiologic study.
- e. Provision of the basis for long-term audit of the results and the success or failure of surveillance to help in worker protection.

With respect to the latter, failure of the NIOSH-OSHA team to periodically audit and determine the value of surveillance plans would be a tragic mistake. I am aware of no such plan at present and believe it should be incorporated into the system virtually at its inception. Without it, necessary changes or corrections and new approaches will not be adopted.

I am pleased, however, to announce that such a core medical examination has been proposed by the physicians sub-committee of the Occupational Safety and Health Administration standards group of the Organization Resources Counselors Inc. It has been presented to the National Advisory Committee on Occupational Safety and Health and has been favorably received. We have learned that this scheme will probably be adopted, at least on a trial basis, to be used when such examinations are given to employees of the Occupational Safety and Health Administration of the U.S. Department of Labor. This is a very encouraging development.

RECORDKEEPING AND SURVEILLANCE

I must point out that our intent was not to encourage OSHA to require examinations of all employed persons. Rather, it is an attempt to standardize OSHA required exams to facilitate compliance, better worker protection, and to aid physicians in doing a better job.

Industrial Hygiene Monitoring Implicit in any venture to protect the health of workers from potentially hazardous agents is a suitable and effective appraisal of actual work place exposure levels. All too often in the past there has been an inadequate history of potential exposure and a lack of precise analytical monitoring. Great strides in developing precise analytical methods have been made in recent years and this effort needs to be pressed vigorously. It is obvious that such data should be coordinated with health surveillance systems; but too often this is not done or not properly understood—especially and understandably by physicians unfamiliar with industrial concerns or toxicological principles.

In this sphere of interest it is essential that there be concern for the possible influence of other unknowns such as coincidental exposures, contaminants in even trace amounts, and variations in content that may occur from time to time.

In no way do I wish to imply or even suggest that industrial hygiene analytical and related functions are in any manner less important than we have always considered them. They are, in fact, the cornerstone and basic foundation of our planning to prevent ill effects from toxic and other harmful effects in the work environment. In my judgment, purely industrial hygiene measures have contributed more than have purely medical activities in reducing the effects of toxic substances, radiation, and other forms of energy, noise, heat and cold stress, excessive work effort, and many other potentially harmful influences on our working people. Nevertheless, the most diligently applied industrial hygiene programs are inherently beset with the possibility of failure in that they cannot possibly provide absolute assurance that the worker is safe. Even if

Threshold Limit Values are observed scrupulously, there is no assurance that the individual adheres to practices that preclude excessive exposure. Breaks in techniques of safe working practices, such as unplanned skin exposure or handling contaminants just prior to meal time or smoking can totally invalidate the most exactly careful precautionary plans. Newer methods utilizing personal sampling monitors which continuously measure the individual's actual environmental exposure may help greatly, but they do not take into account transdermal absorption or any failure based upon sudden, brief exposures at high levels beyond the capability of the instrument to cope. If fail-safe, continuous personal monitoring equipment capable of handling all levels of exposure with reliability are developed, then, except for dermal or oral exposure possibilities, health surveillance might no longer be needed for routine industrial health control. However, as Stokinger has indicated, air-borne concentrations as an index of exposure are also unreliable in situations of mixed exposures with metabolic interaction, individual peculiarities of work habits leading to abnormal intake, and additive exposure off the job. By reflecting all of the possible variables, health surveillance may become sufficiently advanced to provide both an index of exposure and an index of response. Accordingly, only health surveillance techniques, if available for the specific exposure, could ascertain that the individual worker is completely safe and has incurred no adverse effects. Much research and development of new methods is needed before that comfortable condition obtains. In interim it must be hoped that there is sufficient understanding and wisdom to accept the unavoidable but serious limitations with which we are now shackled.

Epidemiology The epidemiologic record related to occupational health and illness (and for that matter, of natural disease, too) traditionally has been appallingly inadequate. Without a valid and usable base of health surveillance and related worker exposure data, the best of epidemiologic schemes will be of only crude quality. This provides cogent emphasis as to the need and

importance of auditing and scientific assessment of the results of our surveillance programs.

Disability and Workers' Compensation The quantification of disability and determination of the degree attributable to occupation truly defies or eludes us technologically today. This precludes the other perspectives of concern (moral, legal, and economic) from being dealt with objectively on a wholly fair and rational basis. Certainly exacting and proper recognition of occupational disease or adverse effects in the input side of the equation is the weakest link in the entire process. No magic answers are apparent in the immediate offing and there is a great need for long-term follow-up of the natural history of disability and its relationship to compensation practices. This particular consideration may not seem related to my topic—but this, plus our humane efforts, becomes the "bottom line" when we fail.

All of these issues indicate that there are many unsolved matters and that our work is clearly cut out for the future. It is obvious that there is an abundant need and clear urgency for major change and realignment of priorities and policies for overall national and occupational health care delivery systems. In order to achieve a successful capability for health surveillance of workers, several special needs emerge:

1. Record systems are critical and much needs to be done to make them more meaningful. Computerization is absolutely essential for correlation with work environmental data, comparative studies, proper and required record retention, and the audit function. Compatibility between systems on areas of primary concern is essential. This in no way precludes individual organizations from embellishing the scope to whatever extent they desire.

2. Improved science is imperative. Despite the remarkable advances in analytic capability, especially in the chemical area, much more is needed and capability in the biomedical sciences is far behind. This lag has, in fact, aggravated our problems in that

we can analyze for levels of exposure far lower than we can determine what, if any, physiologic effect has been induced.

3. In order to meet the work load increase that will be necessitated by health surveillance requirements, persons other than just physicians and nurses will have to become trained and utilized. The adoption of many screening procedures by technicians and other suitable paramedical personnel will become a must. The total task will require involvement of these individuals plus the physicians, nurses, industrial hygienists, toxicologists, and other support personnel engaged in a cohesive team approach.

Much more could be said, and I'm sure that extensive argument could be generated, but this has represented a general airing of the subject and some of the enigmas to be encountered. From these thoughts perhaps three hypotheses can be offered:

1. It is currently impossible to establish a rational basis for assessing the impact of all the combinations and permutations of exposure to many agents—single or multiple with differing characteristics and proportions.

2. The quantification of industrial hygiene measurement and of medical observations both are extremely important—but at this stage in the development of the art they can be highly deceptive and subject to gravely erroneous interpretation. We need better science and deeper understanding, judgment, and wisdom before the numbers will provide all the answers.

3. The sum effect on health is the consequence of interaction among:

- a. A genetically constituted and uniquely constructed human being.
- b. The influence of naturally occurring diseases.
- c. The impact of occupational exposures.
- d. All other environmental and personal endeavor influences.

Consistent with this state of affairs, I believe our greatest efforts should be directed less to the numbers game and more to establishing principles and systems that may help us all to accomplish our intended objective—protecting people from incurring adverse health effects resulting from their work. Finally, I urge the adoption and uniform usage of the term health surveillance.

Mr. GORE. Thank you very much. We will withhold questions until the other members of the panel have concluded their presentations.

I'd like to invite my colleague to deliver his opening statement if he wishes.

Mr. WALKER. Thank you, Mr. Chairman. What I would like to do is just ask unanimous consent that the statement be included in the record at the opening of the hearing and let the witnesses go on.

Mr. GORE. Fine. Without objection.

Dr. Weill, we would like to hear from you. Thank you for coming.

STATEMENT OF HANS WEILL, PROFESSOR OF MEDICINE, TULANE UNIVERSITY

Dr. WEILL. Thank you.

Mr. Chairman, members of the committee, and the staff, I'm pleased to have accepted the invitation to participate in these hearings.

I am professor of medicine at Tulane University at New Orleans and I direct a multidisciplinary research unit in occupational lung diseases funded by the National Heart, Lung and Blood Institute through a specialized center of research grant. Our interests in hazardous exposures found in the workplace vary widely and include mineral dusts, silica and asbestos, organic dusts, cotton, and irritant gases and chemical vapors, chlorine, isocyanates, and formaldehyde. It is the intention of my colleagues and me that the scientific product of our research efforts be utilized in the prevention of occupational lung diseases, acute and chronic disorders which are all potentially preventable. Much of the scientific approach that we employ depends upon the investigation of working populations, both past and present, quantification of their respiratory health, and characterization of their environmental exposures. Ultimately, correlations of the biological and environmental data lead to information concerning dose-response relationships, and, very importantly, how these may be modified by personal or host factors of the worker himself or herself.

The lungs and the airways are unique organs in that they are in constant contact with the inhaled environment and therefore are susceptible to injury from hazardous inhalants. These respiratory diseases that are of interest to our investigative group are invariably multifactorial in cause and they are likely to have as determinants both genetic and environmental factors, and in the latter, using the term in the broad sense, I would include obviously such factors as smoking and infection. Now in the former, there are some specific genetic aberrations that increase the risk of developing certain respiratory diseases. It's clear that the most effective approach to the prevention of these disorders would be a determination of susceptibility to developing the respiratory disorder and, if that susceptibility could be dichotomized—that is, yes or no—the preclusion or exclusion prior to employment of all those found to be susceptible. Regrettably, such is not often the case in the real world. It's just usually not possible to do this prior to employment or exposure.

However, epidemiologic studies of populations exposed to workplace inhalants may identify both exposure and host characteristics which result in increased risk for the development of the adverse respiratory effect, and such risk—thanks to the efforts of our statistical colleagues—are in fact quantifiable. While occasionally this may be possible with our present state of knowledge prior to the time of exposure, therefore leading to the possibility of preemployment screening for high risk individuals, most often indicators of increased risk emerge following initial exposure which may, however, still lead to removal from such exposure before advanced or possibly irreversible respiratory injury has taken place. My first point, therefore, is that while preemployment screening is currently at a very early state of development in meeting the objectives of occupational lung disease prevention, much of the effort probably is going to depend on careful medical surveillance of employed and exposed populations and this careful surveillance even early during employment will in fact serve a similar function.

In our investigative field, there are three major exposure-related respiratory health effects of concern: (1) diffuse pulmonary fibrosis, such as the pneumoconioses, silicosis, and asbestosis; (2) there are acute and chronic airways diseases, the former represented either by occupational asthma or acute bronchitis, and the latter by chronic industrial bronchitis; and (3) the very important occupationally associated respiratory malignancies.

Now dealing with the third category first—that is, the malignant consequences of occupational exposures—it is reasonably safe to indicate to you that we currently have no method to predict which individuals are at increased risk due to genetic factors of developing respiratory cancer. We know, however, that in essentially all occupational causes of respiratory cancer this risk is importantly influenced by cigarette smoking. The interaction between the occupational agent and smoking is substantial, and it is widely agreed that the risk of occupational lung cancer would be strikingly diminished—not eliminated but diminished—in the absence of smoking. The scientific community can produce quantitative estimates of risk, but society and their representatives must decide how to intervene in minimizing these risks.

The risk of developing pneumoconiosis is invariably dose-related in that the higher the average and cumulative exposure, the greater the prevalence and severity of diffuse pulmonary fibrosis associated with this exposure. This has been demonstrated by our group and others in asbestosis and silicosis, but it has not been possible to identify immunologic or personal factors which lead to susceptibility to these conditions. While certain immunologic markers are noted with increased prevalence in workers who have mineral dust diseases, there is no evidence that these serve to predict the condition rather than appearing after the disease is well established.

I might just point out to the committee that, in fact, this is a problem in a number of instances. There may be a marker. The question is, does that marker pre-exist—that is, predate the onset of exposures, or is it simply an attendant consequence of the effects of exposure? And I think that distinction will obviously be important in the development of some concepts of prevention of these conditions.

It should be noted, however, that with adequate medical surveillance throughout employment in our field of respiratory diseases, using simple techniques, such as chest radiography and ventilatory function studies—spirometry—early small opacities appearing on the chest film will often be detectable at a time before pulmonary functional impairment is present. This may allow transfer of a worker before he has received an incremental exposure that could increase the risk of disabling illness. This is particularly true in most workplaces of industrialized nations today, since exposures are far lower than in past decades, and the effects of long latency disorders are much more slowly progressive. And many of the conditions we are discussing are such disorders—that is, it takes a long time for the clinical and laboratory evidence of the disease to appear. These are very slowly progressive. It gives us an opportunity, with careful surveillance begun at the onset of exposure, to detect early effects, preclinical effects, if you will, and presumably intervene in order to prevent more serious and established disease.

Now occupational asthma has become of substantial interest to people interested in occupational health generally. It's characterized—asthma generally—by variable airflow obstruction associated with certain types of workplace exposures. The list of occupations that cause occupational asthma is increasing all the time. There are a variety of them. Some of these are materials known to produce a classical allergic response, but some are chemicals for which sensitization is more difficult to determine, but quite as surely they also can produce occupational asthma.

Let me give you an example. In a castor bean oil processing plant there's a very potent allergen. If one is atopic—that is, has a predisposition to developing a certain type of antibody—that individual's risk may be two, three or four times that of a nonatopic or nonallergic individual for developing sensitization and symptoms related to this allergic or respiratory disorder. This risk, as I say, can be quantified. The question arises, is that a substantial enough risk to preclude employment? And that's a decision that I think must be shared widely and not made just by the medical profession.

Bronchial hyperresponsiveness may be a genetically determined factor leading to increased risk of developing occupational asthma, or may be acquired as the result of such an exposure prior to the onset of clinically overt asthma. Certainly this measurement may be useful in preemployment assessment in selected industries; we and others are looking at that to see whether or not we can identify, by hyperresponsiveness of the airways, those individuals who are most likely to develop occupational asthma. We don't know yet and it's too early to use that measurement as a screening technique.

Finally, in regard to occupational asthma where immunologic methods can provide information on specific immunoreactivity. That is, has a person become sensitized to a workplace allergen? There may be reasons to remove sensitized workers—detected by skin or blood tests—from further exposure prior to the time that clinical symptoms appear. Also, if sensitization is occurring, there may also be very good reason to lower airborne concentrations of these allergens in order to reduce sensitization risk in others.

Industrial bronchitis has been recognized in certain dusty industries and is receiving some attention in other workplace conditions where irritant inhalants may be present, such as in the chemical industry. Since bronchitis is importantly causally associated with cigarette smoking and is a common condition in the general population, the ascertainment of industrial bronchitis—that is, the part of bronchitis that we would attribute to the workplace—is difficult, and predictors of this condition are therefore not available. Bronchitis may be associated only with cough and expectoration, but produces disability and shortened life span if it causes progressive airways obstruction. Let me emphasize that point. If in fact we are dealing with workplace exposure that may produce chronic airways obstruction, early monitoring of lung function over time, measured in a standardized way probably will allow us, as our investigations have shown, to detect rather modest increases in decline which may identify those individuals who are on the fast track downward and are presumably responding adversely to the environment. Rapid decliners have been detected in smoking populations. Surveillance then, in a sense, early in the course of employment is a surrogate, if you will, of preemployment screening, but just as useful and certainly much more available. As has been demonstrated in longitudinal studies of smokers, intervention at these early times when one of these fast decliners is identified, can in fact prevent further accelerated decline in function.

In summary, it must be conceded that the "state of the art" in most areas of medicine, including lung diseases, does not often permit us to predict and quantify increased risk for developing work-related lung disorders. I have mentioned some exceptions. However, careful surveillance of respiratory health, using simple methods, in workers exposed to known or potentially hazardous inhalants, will often meet the objective of prevention of serious disease. Carcinogenesis may be the exception, with our present state of knowledge. In regard to the question of whether permissible workplace exposure standards can protect all workers, even those who ultimately prove to be susceptible, it is unlikely that this can be achieved, but we will come closer to this objective as we improve capability of identifying susceptible individuals and minimizing or preventing their exposure. In this regard we must be reminded that even susceptibility does not preclude does relatedness, and there may often be levels of exposure which can be tolerated by individuals who are susceptible to a particular agent, a fact recently demonstrated in our studies of workers exposed to isocyanates. While this may be demonstrable for acute responses, such as asthma, it is much more difficult to assess in the short term for chronic effects. This would become possible in the airways disorders if one could correlate the acute and chronic effects, a subject of considerable interest in cotton dust exposure. Whoever makes judgments concerning the acceptance or nonacceptance of various risks attendant upon occupational exposure, the judgments must be made on the basis of the best scientific information. It is the responsibility of groups like ours to provide accurate data and subsequent analyses on which public policy decisions can be made. There will always be an implicit, if not explicit, balancing of health effects and economic considerations. These judgments are best

spread widely over segments of society which have legitimate concern. Risk assessment will lead to rational prioritizing of our limited resources.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Weill follows:]

PREPARED STATEMENT OF HANS WEILL, M.D.

At Tulane, I direct a multidisciplinary research unit in occupational lung diseases funded by the National Heart, Lung and Blood Institute through a Specialized Center of Research grant. Our interests in hazardous exposures found in the workplace vary widely and include mineral dusts (e.g., silica and asbestos), organic dusts (e.g., cotton), and irritant gases and chemical vapors (e.g., chlorine, isocyanates and formaldehyde). It is the intention of my colleagues and me that the scientific product of our research efforts be utilized in the prevention of occupational lung diseases, acute and chronic disorders which are all potentially preventable. Much of the scientific approach that we employ depends upon the investigation of working populations, quantification of their respiratory health, and characterization of their environmental exposures. Correlations of the biological and environmental data lead to information concerning dose-response relationships, and how these may be modified by personal or host factors of the worker. The respiratory diseases that we study are invariably multifactorial in cause and are likely to have as determinants both genetic and environmental (used in the broad sense) factors. Among the former are included a few specific genetic aberrations that increase the risk of developing certain respiratory diseases, and among the latter are such heterogeneous factors as smoking and infection, as well as the specific occupational inhalants which are generally the focus of our attention. It is clear that the most effective approach to the prevention of these disorders would be a determination of susceptibility to developing the respiratory disorder and, if that susceptibility could be dichotomized (i.e., yes or no), the preclusion or exclusion prior to employment of all those found to be susceptible. Regrettably, such is not often the case in the real world.

However, epidemiologic studies of populations exposed to workplace inhalants may identify both exposure and host characteristics which result in increased risk for the development of the adverse respiratory effect, and such risk is quantifiable. While occasionally this may be possible with our present state of knowledge prior to the time of exposure, therefore leading to the possibility of pre-employment screening for high risk individuals, most often indicators of increase risk emerge following initial exposure which may, however, still lead to removal from such exposure before advanced or possibly irreversible respiratory injury has taken place. My first point, therefore, is that while pre-employment screening is currently at a very early stage of development in meeting the objectives of occupational lung disease prevention, careful medical surveillance of employed (and exposed) populations may serve a similar function.

In our investigative field, there are three major exposure-related respiratory health effects of concern: (1) diffuse pulmonary fibrosis, such as the pneumoconioses, silicosis and asbestosis; (2) acute and chronic airways responses, the former represented either by occupational asthma or acute bronchitis, and the latter by chronic industrial bronchitis; and (3) respiratory malignancies.

Dealing with the third category first, it is reasonably safe to indicate to you that we currently have no method to predict which individuals are at increased risk due to genetic factors of developing respiratory cancer. We know, however, that in essentially all occupational causes of respiratory cancer this risk is importantly influenced by cigarette smoking. The interaction between the occupational agent and smoking is substantial, and it is widely agreed that the risk of occupational lung cancer would be strikingly diminished in the absence of smoking. The scientific community can produce quantitative estimates of risk, but society and their representatives must decide how to intervene in minimizing these risks.

The risk of developing pneumoconiosis is invariably dose-related in that the higher the average and cumulative exposure, the greater the prevalence and severity of diffuse pulmonary fibrosis associated with this exposure. This has been demonstrated by our group and others in asbestosis and silicosis, but it has not been possible to identify immunologic or personal factors which lead to susceptibility to these conditions. While certain immunologic markers are noted with increased prevalence in workers who have mineral dust diseases, there is no evidence that these serve to predict the condition rather than appearing after the disease is well established. It should be noted, however, that with adequate medical surveillance throughout employment using simple techniques, such as chest radiography and

ventilatory function studies (spirometry), early small opacities appearing on the chest film will often be detectable at a time before pulmonary functional impairment is present. This may allow transfer of a worker before he has received an incremental exposure that could increase the risk of disabling illness. This is particularly true in most workplaces of industrialized nations today, since exposures are far lower than in past decades, and the effects of long latency disorders are much more slowly progressive.

Occupational asthma is characterized by variable air flow obstruction associated with certain types of workplace exposures. This condition can be caused not only by materials known to produce a classical allergic response, but by simple chemicals for which sensitization is more difficult to determine. For some causes an atopic (classically allergic) predisposition constitutes a risk factor for developing sensitization to the workplace allergen. This risk is quantifiable, and again the question must be raised whether such individuals can or should be excluded from certain of these jobs. The biomedical investigator can provide the data quantifying risk; others must participate in the important social and economic decisions. Bronchial hyperresponsiveness may be a genetically determined factor leading to increased risk of developing occupational asthma, or may be acquired as the result of such an exposure prior to the onset of clinically overt asthma. Certainly this measurement may be useful both in pre-employment assessment in selected industries, as well as serial measurement for the earliest signs of variable air flow limitation. Finally, in regard to occupational asthma where immunologic methods can provide information on specific immunoreactivity, i.e., that a person has become sensitized to a workplace allergen, there may be reasons, even in an asymptomatic but sensitized individual, to first remove that person from further exposure to the sensitizing agent, and to then reduce exposures in order to prevent sensitization of others.

Industrial bronchitis has been recognized in certain dusty industries and is receiving some attention in other workplace conditions where irritant inhalants may be present, such as in the chemical industry. Since bronchitis is importantly causally associated with cigarette smoking, and is a common condition in the general population, the ascertainment of industrial bronchitis is difficult, and predictors of this condition are therefore not available. Bronchitis may be associated only with cough and expectoration, but produces disability and shortened life span if it causes progressive airways obstruction. The latter can be ascertained early by serial lung function measurements available to those responsible for monitoring occupational health, and must be considered when there is excess annual decline in pulmonary function parameters. Again, as has been demonstrated with smoking, intervention can be expected to reverse the accelerated decline in function.

In summary, it must be conceded that the "state of the art" in most areas of medicine, including lung diseases, does not often permit us to predict and quantify increased risk for developing work-related lung disorders. I have mentioned some exceptions. However, careful surveillance of respiratory health, using simple methods, in workers exposed to known or potentially hazardous inhalants, will often meet the objective of prevention of serious disease. Carcinogenesis may be the exception, with our present state of knowledge. In regard to the question of whether permissible workplace exposure standards can protect all workers, even those who ultimately prove to be susceptible, it is unlikely that this can be achieved, but we will come closer to this objective as we improve capability of identifying susceptible individuals and minimizing or preventing their exposure. In this regard we must be reminded that even susceptibility does not preclude dose-relatedness, and there may often be levels of exposure which can be tolerated by individuals who are susceptible to a particular agent, a fact recently demonstrated in our studies of workers exposed to isocyanates. While this may be demonstrable for acute responses, such as asthma, it is much more difficult to assess in the short-term for chronic effects. This would become possible in the airways disorders if one could correlate the acute and chronic effects, a subject of considerable interest in cotton dust exposure. Whoever makes judgements concerning the acceptance or non-acceptance of various risks attendant upon occupational exposure, the judgements must be made on the basis of the best scientific information. It is the responsibility of groups like ours to provide accurate data and subsequent analyses on which public policy decisions can be made. There will always be an implicit, if not explicit, balancing of health effects and economic considerations. These judgements are best spread widely over segments of society which have legitimate concern. Risk assessment will lead to rational prioritizing of our limited resources.

Mr. GORE. Thank you very much.

Mr. Samuels, welcome. And without objection, your entire text will be put in the record. We invite you to present any or all of it as you see fit.

STATEMENT OF SHELDON SAMUELS, DIRECTOR, HEALTH, SAFETY, AND ENVIRONMENT INDUSTRIAL UNION DEPARTMENT, AFL-CIO, ON BEHALF OF HOWARD D. SAMUEL, PRESIDENT OF THE DEPARTMENT

Mr. SAMUELS. Thank you, Mr. Gore and Mr. Walker. Let me thank you and your staff for putting light on what potentially poses the most difficult problem workers will have to face in the coming decade.

The genetic factor in occupationally related disease is one factor in a broader system of disease explanation. The system is useful if it bears fruit in prevention or intervention of disease development. There is nothing about such a system that demands that we characterize it as "The Truth" or "The Cause." The system is simply a scientific model that either is or is not heuristic.

The model finds expression, whether in blood enzyme or anatomical differences, in the gene as a physiological agent, but "primarily," noted Sewall Wright, as a mere "hypothetical entity postulated to make sense out of the results of breeding experiments."

Because of the power of the genetic factor, partly a function of historical visibility, there is a rising tendency to isolate and favor it, especially since some of the other cofactors in the system of disease explanation—personal habits, lifestyle, diet, community environment—are wearing out their propagandic usefulness. For some, there is a need for new fads to rationalize the continuing tragedy in which the workplace is permitted—indeed, designed—to uniquely and unnecessarily contribute to death and sickness. Placing the genetic factor in a socially and individually meaningful context at this stage in the management of risk and high risk populations is still possible, but not without congressional action.

There has been a long-held and strong consensus among scientists that the final expression of any gene depends upon the complex end results of physico-chemical reactions started by the gene and other factors. The reactions can be influenced by the internal and external environments of the organism and by other genes. Differences in environment result in marked differences in the expression of genes. Indeed, many geneticists hold that no statement about genetic differences has meaning unless the environment in which the gene manifests itself is specified.

If we understand the way in which a gene operates to exert its effects, we may be able—by monitoring genetic change and by controlling conditions—to limit the effect of the gene to some particular—or even no—effect.

Clearly, given this understanding, significant new tools can be developed in our struggle to control the environments created by man to prevent disease or to intervene when environmentally induced damage has already occurred.

A barrier to this understanding is the failure to understand concurrently that organisms are not pieces of putty, infinitely moldable by infinitesimal degrees in any direction, but are, rather, complex and resilient structures.

There will be those who see in genetics an opportunity to ignore this organic limitation as part of their continuous effort to bypass environmental control, to attempt to mold man to the machine and, failing that, to eliminate some men either from work or, by distortion of science, from just care and compensation for damaged related to workplace exposures. This cannibalistic approach flies in the face of the scientific reality that there is an added burden of occupationally attributable disease that will be eliminated only if the occupational exposure is eliminated, that is, there is a burden independent of genetics and other factors extraneous to the workplace.

The dean of American industrial toxicology, Norton Nelson, states the moral corollary of the scientific reality of the added burden:

* * * The reduction of the frequency of human cancer from occupational exposures to an insignificant level is a practical and attainable objective * * * work assignments (should) be open to all persons mentally and physically capable of fulfilling the task regardless of special genetic or sex limitations * * * controls should be sufficiently strict so that even the most sensitive components of the population are protected.

I submit that research has always been, and should be, stimulated by practical needs of society. Research directed toward the identification of chemical and physical disease factors—Dr. Nelson's life work—and their control by engineering design in the workplace to meet this objective is a moral necessity and should not be diminished in any way. But fulfilling this need takes nothing from other equally important research that logically follows from fundamental discoveries in biology that have taken place in the past generation.

Knudson estimates that individuals with a predisposition to cancer imposed by environmental variation in the absence of genetic variation, or imposed by both factors, constitute 70 percent to 80 percent of the afflicted in industrial nations. If this is a supportable "fact," is it useful to identify and sort out the genetic factor?

The deficient ability of individuals to repair damaged DNA and consequent cancer-proneness appears to be genetically identifiable. What does such damage mean? Would genetic analysis of those with impaired cell duplicating mechanisms aid in the identification of the cancer prone? Would such identification be useful?

Peto has some negative answers to these questions: "Genetic susceptibility to cancer may be worthy of study more for the understanding of mechanisms of carcinogenesis that it affords than for the immediate benefits of early detection or genetic counseling." Peto's case is based in part on an analysis of cancer rates in which an inflection of the curves fitted to some populations in which susceptibles are subtracted can be accounted for not by the elimination of susceptibles, but by other effects such as environmental differences. But his argument is also based on the observation that "even if there are substantial differences in susceptibility it is unlikely that anyone is immune to any cancer." Thus, even if susceptibles were identifiable, their removal from exposure would not eliminate the need to protect the nonsusceptibles.

Evidence from the study of other, nonneoplastic disease would indicate that the value of genetic counseling cannot be written off so easily.

Kueppers looked at the deficiency in a variant of a serum protein—alpha-1-antitrypsin—in relation to chronic obstructive pulmonary disease. Most but not all with the deficiency develop the disease, but without smoking a more benign course is found. Cigarette smoking doubles the effect, illustrating how an environmental condition can determine the severity of a genetic expression.

In the rare cases of this kind, even now, counseling of a known carrier may be a helpful step in the management of disease. But the rarity of these cases makes population screening for this kind of deficiency impractical. General screening for "cancer-proneness," whatever that is, would be even less useful, given the current state of knowledge.

The case for genetic monitoring is very different. Unlike genetic screening—one-time tests for known heritable disease, monitoring would utilize repeated short-term tests on groups or individuals to assess genetic damage in somatic or germ cells. Ideally, such programs promise early warning of toxicity and early detection of damaged and, therefore, high-risk populations.

While some techniques appear to be sufficiently developed for application, serious questions about their immediate use have been raised which in part explain their limited incorporation within the practice of industrial medicine. Nevertheless, especially where genetic damage can be associated with changes in the immune system, the potential for the reduction of disease is so great that a high national priority for rapid research and development of these techniques is justified.

Each affected population in our society has a right justified by sad history to fear the consequences of technological/scientific innovation. The labor movement is no exception. Viewed as a renewable resource, a mere commodity in the workplace, workers and their families have always been the first to subsidize new industrial processes with their health and even their lives, and the last to benefit materially. Witness silicosis in King Solomon's mines, lead and mercury poisoning among potters and hatters at the beginning of the industrial era, cancer among dyeworkers in the prior and in this generation, and the widespread human devastation seen today in pesticides and plastics manufacture. Nevertheless, we cannot and should not foreclose change. We need to control, not to stop, the dynamics of our society.

If the same kind of governmental safeguards used to regulate the adverse consequences to workers—blacklisting, drugging—subject to biological monitoring for lead exposure are instituted for general genetic monitoring in a workplace, widespread support for genetic research and its application in the workplace can be expected. At the same time the research is conducted, the creating scientist must take responsibility for suggesting and designing appropriate safeguards and supporting the implementation of these safeguards prior to application. It is a congressional and union responsibility to see that these measures are taken by the administrative agencies such as the Occupational Safety and Health Administration.

Genetic screening, however, is another and more difficult case. Fortunately, given the primitive state of the science, we have time for the parallel innovation of social safeguards that will require more than the protections of the Occupational Safety and Health Act.

Genetic screening has a potential for unjust application and shortsighted social policy. The probability of overreaction that would unfairly reduce employment opportunities for thousands—perhaps millions—of men and women is established by past performance. Normal marketplace corporate policies would discard human beings—correctly or incorrectly from a biological perspective—on a scrap heap of the impoverished. The social disruption could tear the fabric of society. Can we and should we create a race of susceptibles consciously sacrificed on the altar of the “greatest good for the greatest number”? Degraded by deprivation of the generic rights—the right to live and the means to be free—should we create by social and governmental inaction a cast of subhumans? Far-fetched? Who would employ these susceptibles, who would protect their dignity and place in the community? Here is the stuff by which war and revolution have been made and by which human progress has been destroyed.

And what is a susceptible to cancer or any other disease? There is no norm except in a statistical sense. We each have an almost infinite range of genetic differences which are deficiencies in relation to a selected standard. Who should set such standards? Are any of us willing to give such power unqualified to any other person?

Yet, having said this, if it becomes feasible and reliable, genetic screening should be done—on one condition: Industrial genetic screening should only take place in a society that has created a system of screening within neutral community structures that protect the individual and his family during the counseling process. It must not take place in the coercive milieu of the typical industrial setting.

Acceptable patient-physician relationships cannot usually be developed and maintained in a setting in which confidentiality and trust between the doctor and the worker is secondary to the interests of the corporation. Confidentiality, access to records for research, treatment and compensation, physician independence must be guaranteed. There are existing laws that can be used, but essentially a new Federal regulatory function would have to be recognized and created.

Meanwhile, through your oversight and appropriations authority, the Congress must strengthen the administration of laws already in place. For example, after 10 years of effort, a worker's right of access to his own medical and environmental records—guaranteed in the Occupational Safety and Health Act—was finally implemented by regulation last year. That standard has come under heavy attack by management. The new administration proposes—in obedience to management's instruction—to inflict the threat of financial punishment to any worker or his family who requests access to existing records—including the results of any genetic screening that may have taken place.

We cannot and should not stop genetic research. We can and should stop its application when ethical application is not possible. [The prepared statement of Mr. Samuels follows:]

PREPARED STATEMENT OF HOWARD D. SAMUELS

SCIENCE OR RATIONALIZATION

The genetic factor in occupationally related disease is one factor in a broader system of disease explanation. The system is useful if it bears fruit in prevention or intervention of disease development. There is nothing about such a system that demands that we characterize it as The Truth or The Cause.

The model finds expression, whether in blood enzyme or anatomical differences, in the gene as a physiological agent, but "primarily," noted Sewall Wright, (1945) as a mere "hypothetical entity postulated to make sense out of the results of breeding experiments."

Because of the power of the genetic factor, partly a function of historical visibility, there is a rising tendency to isolate and favor it, especially since some of the other co-factors in the system of disease explanation—personal habits, life-style, diet, community environment—are wearing out their propagandic usefulness. For some, there is a need for new fads to rationalize the continuing tragedy in which the workplace is permitted—indeed, designed—to uniquely and unnecessarily contribute to death and sickness. Placing the genetic factor in a socially and individually meaningful context at this stage in the management of risk and high risk populations is still possible, but not without Congressional action.

There has been a long held and strong consensus among scientists (Boyd 1950), that the final expression of any gene depends upon the complex end results of physico-chemical reactions started by the gene and other factors. The reactions can be influenced by the internal and external environments of the organism and by other genes. Differences in environment result in marked differences in the expression of genes. Indeed, many geneticists hold that no statement about genetic differences has meaning unless the environment in which the gene manifests itself is specified.

If we understand the way in which a gene operates to exert its effects, we may be able—by monitoring genetic change and by controlling conditions—to limit the effect of the gene to some particular (or even no) effect.

Clearly, given this understanding, significant new tools can be developed in our struggle to control the environments created by man to prevent disease or to intervene when environmentally-induced damage has already occurred.

A barrier to this understanding is the failure to understand concurrently that "organisms are not pieces of putty, infinitely moldable by infinitesimal degrees in any direction, but are, rather, complex and resilient structures . . ." (Gould 1981).

There will be those who see in genetics an opportunity to ignore this organic limitation as part of their continuous effort to bypass environmental control, to attempt to mold man to the machine and, failing that, to eliminate some men either from work or, by distortion of science, from just care and compensation for damage related to workplace exposures. This cannibalistic approach flies in the face of the scientific reality that there is an added burden of occupationally-attributable disease that will be eliminated only if the occupational exposure is eliminated, that is, there is a burden independent of genetics and other factors extraneous to the workplace.

The dean of American industrial toxicology, Norton Nelson, states the moral corollary of the scientific reality of the added burden: ". . . The reduction of the frequency of human cancer from occupational exposures to an insignificant level is a practical and attainable objective . . . work assignments (should) be open to all persons mentally and physically capable of fulfilling the task regardless of special genetic or sex limitations . . . controls should be sufficiently strict so that even the most sensitive components of the population are protected." (Nelson 1981).

I submit that research has always been, and should be, stimulated by practical needs of society. Research directed toward the identification of chemical and physical disease factors (Dr. Nelson's life work) and their control by engineering design in the workplace to meet this objective is a moral necessity and should not be diminished in any way. But fulfilling this need takes nothing from other equally important research that logically follows from fundamental discoveries in biology that have taken place in the past generation.

Knudson (1977) estimates that individuals with a predisposition to cancer imposed by environmental variation in the absence of genetic variation, or imposed by both

factors, constitute 70 to 80 percent of the afflicted in industrial nations. If this is a supportable "fact," is it useful to identify and sort out the genetic factor?

The deficient ability of individuals to repair damaged DNA and consequent cancer-proneness appears to be genetically identifiable (Strauss 1981). What does such damage mean? Would genetic analysis of those with impaired cell duplicating mechanisms aid in the identification of the cancer-prone? Would such identification be useful?

Peto (1980) has some negative answers to these questions: "Genetic susceptibility to cancer may be worthy of study more for the understanding of mechanisms of carcinogenesis that it affords than for the immediate benefits of early detection or genetic counseling." Peto's case is based in part on an analysis of cancer rates in which an inflection of the curves fitted to some populations in which susceptibles are abstracted can be accounted for not by the elimination of susceptibles, but by other effects such as environmental differences. But his argument is also based on the observation that "even if there are substantial differences in susceptibility it is unlikely that anyone is immune to any cancer." Thus, even if susceptibles were identifiable, their removal from exposure would not eliminate the need to protect the non-susceptibles.

Evidence from the study of other, non-neoplastic disease would indicate that the value of genetic counseling cannot be written off so easily.

Kueppers (1978) looked at the deficiency in a variant of a serum protein (alpha₁-antitrypsin) in relation to chronic obstructive pulmonary disease. Most but not all with the deficiency develop the disease, but without smoking, a more benign course is found. Cigarette smoking doubles the effect, illustrating how an environmental condition can determine the severity of a genetic expression.

In the rare cases of this kind, even now, counseling of a known carrier may be a helpful step in the management of disease. But the rarity of these cases makes population screening for this kind of deficiency impractical. General screening for "cancer proneness" would be even less useful, given the current state of knowledge.

The case for genetic monitoring is very different. Unlike genetic screening (one-time tests for known heritable disease), monitoring would utilize repeated short-term tests on groups or individuals to assess genetic damage in somatic or germ cells. Ideally, such programs promise early warning of toxicity and early detection of damaged and, therefore, highrisk populations.

While some techniques appear to be sufficiently developed for application (Fabricant and Legator 1981), serious questions about their immediate use (Dabney 1981) have been raised which in part explain their limited incorporation within the practice of industrial medicine. Nevertheless, especially where genetic damage can be associated with changes in the immune system (Selikoff 1981), the potential for the reduction of disease is so great that a high national priority for rapid research and development of these techniques is justified.

CONDITIONS FOR GENETIC SCREENING

Each affected population in our society has a right justified by sad history to fear the consequences of technological/scientific innovation. The labor movement is no exception. Viewed as a renewable resource, a mere commodity in the workplace, workers and their families have always been the first to subsidize new industrial processes with their health and even their lives, and the last to benefit materially. Witness silicosis in King Solomon's mines, lead and mercury poisoning among potters and hatters at the beginning of the industrial era, and even today, cancer among dye workers in the prior and in this generation, and the widespread human devastation seen today in pesticides and plastics manufacture. Nevertheless, we cannot and should not foreclose change. We need to control not to stop the dynamics of our society.

If the same kind of governmental safeguards used to regulate the adverse consequences to workers (blacklisting, drugging) subject to biological monitoring for lead exposure are instituted for general genetic monitoring in a workplace, widespread support for genetic research and its application in the workplace can be expected. At the same time the research is conducted, the creating scientist must take responsibility for suggesting and designing appropriate safeguards and supporting the implementation of these safeguards prior to application. It is a Congressional and union responsibility to see that these measures are taken by the administrative agencies such as the Occupational Safety and Health Administration.

Genetic screening, however, is another and more difficult case. Fortunately, given the primitive state of the science, we have time for the parallel innovation of social safeguards that will require more than the protections of the Occupational Safety and Health act.

Genetic screening has a potential for unjust application and shortsighted social policy. The probability of overreaction that would unfairly reduce employment opportunities for thousands—perhaps millions—of men and women is established by past performance. Normal “marketplace” corporate policies would discard human beings (correctly or incorrectly from a biological perspective) on a scrap heap for the impoverished. The social disruption could tear the fabric of society. Can we and should we create a race of “susceptibles” consciously sacrificed on the altar of the “greatest good for the greatest number”? Degraded by deprivation of the generic rights—the right to live and the means to be free—should we create by social and governmental inaction a caste of sub-humans? Farfetched? Who would employ these “susceptibles”, who would protect their dignity and place in the community? Here is the stuff by which war and revolution have been made and by which human progress has been destroyed.

And what is a “susceptible”, to cancer or any other disease? There is no “norm” except in a statistical sense. We each have an almost infinite range of genetic differences which are deficiencies in relation to a selected standard. Who should set such standards? Are any of us willing to give such power unqualified to any other person?

Yet, having said this, if it becomes feasible and reliable, genetic screening should be done—on one condition:

Industrial genetic screening should only take place in a society that has created a system of screening within neutral community structures that protect the individual and his family during the counseling process. It must not take place in the coercive milieu of the typical industrial setting.

Acceptable patient-physician relationships cannot usually be developed and maintained in a setting in which confidentiality and trust between the doctor and the worker is secondary to the interests of the corporation. Confidentiality, access to records for research, treatment and compensation, physician independence must be guaranteed. There are existing laws that can be used, but essentially a new federal regulatory function would have to be recognized and created.

Meanwhile, through your oversight and appropriations authority, the Congress must strengthen the administration of laws already in place. For example, after ten years of effort, a worker's right of access to his own medical and environmental records (guaranteed in the Occupational Safety and Health Act) was finally implemented by regulation last year. That standard has come under heavy attack by management. The new Administration proposes—in obedience with management's instruction—to inflict the threat of financial punishment to any worker or his family who requests access to existing records—including the results of any genetic screening that may have taken place.

We cannot and should not stop genetic research. We can and should stop its application when ethical application is not possible.

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Mr. SHAMANSKY. Mr. Samuels, I couldn't help wondering during your testimony, what is the history of the Industrial Union Department of the AFL-CIO in making such items as this one of the

important bargaining goals? I mean, you say here that this should be a new Federal regulatory function and I want to know what the voluntary sector—the private sector has done. Why haven't your unions been bargaining consistently with the employers to establish your own system for doing this?

Mr. SAMUELS. The apparatus for dealing with this problem has in fact been a subject of collective bargaining for a very long time. It has even become a strike issue. I can go back to the strike, I think in 1969, against the Johns Mansville plant in New Jersey, in which a major issue was the right of access of the workers to their own medical records.

Mr. SHAMANSKY. That's just one narrow facet. I'm talking about the general problem about being a major goal in collective bargaining of the AFL-CIO. I don't mind telling you that this layman hasn't heard that being a crucial issue. Times for lunch, you know, cents per hour—I hear that. But I don't remember having heard what we're talking about here today.

Mr. SAMUELS. We recognize the fact that we don't represent all the workers in this country.

Mr. SHAMANSKY. I'm talking about your workers, nobody else. I'm talking about your own goals.

Mr. SAMUELS. I want to define this very carefully for you, Congressman. Having that limitation——

Mr. SHAMANSKY. What limitation?

Mr. SAMUELS. The limitation of not representing most workers in that industry.

Mr. SHAMANSKY. I understand that.

Mr. SAMUELS. What that means is that what you can do with noneconomic issues is very limited. But given this limitation, in fact, we have as a major goal the alteration of the conditions—we are looking at the apparatus—under which genetic screening could take place. For example, we do try to create an equitable means through collective bargaining—and there's a Labor Department study to support this——

Mr. SHAMANSKY. Let me ask you this. Are you satisfied with the progress you have made with your own people?

Mr. SAMUELS. No, we're not.

Mr. SHAMANSKY. I hope you understand what I'm concerned about. You call for new Federal regulatory function and yet I don't even see your own shop doing much about it in any significant fashion.

Mr. SAMUELS. I would be happy to give you for the record a detailed analysis of the progress that we have indeed made in this area.

Mr. SHAMANSKY. I think that would be very important because I'm just—as I say, I'm getting very subjective on this sort of thing. I couldn't tell up until today that there was much of a concern.

Mr. SAMUELS. There is, sir. There have been wildcat strikes.

Mr. SHAMANSKY. I'm talking about of your union, as a major issue, because it affects the lives of your people.

Mr. SAMUELS. It is a matter of deep concern. The way in which our department, by the way, influences collective bargaining is through what we call coordinated bargaining. We, in fact, have been assisting the committees through which we operate, which

are committees of local unions, in the development of contract language to protect their members. This is not a recent thing. As the Labor Department study indicates, it is a growing thing.

Now I won't belittle the difficulty of having the local unions who are the final decisionmakers in this process understand the importance of this.

Mr. SHAMANSKY. But are you in effect telling me that you don't have a very good handle on noneconomic issues like this with respect to urging the locals to make a stand on it?

Mr. SAMUELS. Until they are faced with a crisis—and right now there are very few actual instances of genetic counseling—we will not get a great deal of commitment. All we can do—and we are doing this I think effectively—is try to affect the structure within which such genetic counseling could take place—access to records and increasingly something to say about how the medical programs in plants are being conducted. And so I think that we have made an effort and we will continue to make an effort. As more companies begin to do genetic screening and involve themselves in genetic counseling, I think that you will find that workers in general will realize the risks under which they will be operating.

Mr. SHAMANSKY. Thank you.

Dr. DIXON, you made some reference to some studies that have been made. Would you tell us which studies and can you tell us who conducted them?

Dr. DIXON. I'm not sure I know which ones you're referring to.

Mr. SHAMANSKY. On page 3 of your testimony. It's the first full paragraph on page 3.

Dr. DIXON. Well, this came from a review of a lot of literature and I didn't cite that. I have literature references in there, but there have been several summary articles, one of the most important of which was the one Mr. Samuels referred to of Betty Dabney in the most recent issue of the Journal of Occupational Medical Association.

Mr. SHAMANSKY. If you're familiar with this area, what record is there of employers working with unions in establishing the most objective and scientifically defensible screening process or is it simply an adversarial procedure?

Dr. DIXON. I don't know of any work that's been done with the unions. I know of a very limited amount of work being done in companies. There are only two or three of which we are generally aware and these have all been pretty much research projects with the exception of one in which the Du Pont Co. reported in the literature a year or two ago about doing voluntary screening for the sickle cell trait for their black employees, which was at the request of the black employees. Most of the work has been really experimental to see if there was anything that could be done that would be helpful in protecting the worker.

Mr. SHAMANSKY. Are you satisfied overall that this is a scientifically defensible procedure?

Dr. DIXON. My judgment is that that work which has been done thus far that I'm aware of is that way.

Mr. SHAMANSKY. I'm curious. If it's for the benefit of the worker—this is directed to the panel in general—why the conflict?

Dr. DIXON. I think it's rather evident, as Mr. Samuels has said and I implied, there certainly are opportunities here wherein this could be abused, as any other health facet could be if it's used in a false manner to deprive people from work that they should be entitled to or in any way were a part of a scheme against workers, this could be very bad.

Mr. SHAMANSKY. What I'm trying to get at, I understand the dangers of abuse. I'm curious about the lack of use in the first place, before we ever get to the abuse part.

Dr. DIXON. The lack of use currently?

Mr. SHAMANSKY. Yes.

Dr. DIXON. The lack of use I think is very wise because we don't have a sound basis scientifically for doing any of the tests at this point except as a research tool.

Mr. SHAMANSKY. Dr. Weill, do you think we're being—

Dr. DIXON. That is, in terms of genetic screening now. We did say other health screening, which is done—and Dr. Weill made mention of a number of things that are very useful and I did, too, in the sense of general health testing that we think are extremely helpful for workers.

Mr. SHAMANSKY. Genetics?

Dr. DIXON. Genetic testing just has not panned out at all so far.

Mr. SHAMANSKY. Dr. Weill?

Dr. WEILL. The thrust of my comments essentially was that while there were a few genetic clues to susceptibility, essentially all of those do not apply to causal association between worker exposure and a respiratory disorder, and because of the importance of early indicators of respiratory disease in terms of prevention of further impairment when in fact it may interfere with physical activities and even longevity, my plea was that great efforts be made on early surveillance in the workplace, which in a sense—

Mr. SHAMANSKY. Surveillance?

Dr. WEILL. Surveillance of respiratory health by simple methods.

Mr. SHAMANSKY. That's not necessarily a question of genetics?

Dr. WEILL. That's correct, but genetic influences appear because there are some people, for instance, who are more susceptible to developing occupational asthma because they are allergic, because they have a diathesis for developing hay fever or asthma, and therefore, if they go into a workplace that has an allergen as part of its process—

Mr. SHAMANSKY. Which leads me to this question. So what's new?

Dr. WEILL. What is new I suppose is there are refined methods today of early detection of disease which in a sense can be used to, No. 1, clean up the workplace; and, No. 2, change the exposure of the individual so that the person who seems to be at risk of developing clinically apparent overt disease can in fact be prevented from doing so by modifying his or her exposure. That too, of course, leads to potentially the same kind of problems—what would one consider an early indicator of such an impending disease?

Mr. SHAMANSKY. Are you satisfied that the criteria have been sufficiently well established that you can get some general agreement?

Dr. WEILL. In some instances in the scientific community, yes, there is general agreement. For instance, we have a pretty good idea in terms of airways function of bronchitic and emphysematous conditions when in fact an annual decline in lung function is clearly excessive, if such a decline is over what one would predict on the basis of aging alone. If such a decline were to occur and nonoccupational factors did not seem to be causally related; then, yes, as a scientist—and I think I would have a lot of agreement on this—such a person should be counseled to stop exposure to a particular injurious agent.

Mr. SHAMANSKY. Mr. Samuels, listening to the remarks of Dr. Weill, wouldn't you be the first to agree that that's a very healthy procedure?

Mr. SAMUELS. We mentioned Du Pont and it's one of the few companies that's entered into this. There is no union to enter into the process in that company except in a few plants and the consequence is that the ability of the worker to have some meaningful input and meaningful protection essentially does not exist. That's why we need neutral community structures for the counseling.

Mr. SHAMANSKY. Excuse me. Again, I'm resisting—every time you come into that I find myself involuntarily resisting the call for some neutral thing when I don't even see a partisan effort to make heads or tails out of this thing.

Mr. SAMUELS. Well, the fear comes from the past history. In the past we have not had genetic screening. We have other kinds of screening, for example, and that's what has built—

Mr. SHAMANSKY. How prevalent do you think the genetic screening really is?

Mr. SAMUELS. I don't think it's prevalent widely at all at this point. It's a potential problem.

Mr. SHAMANSKY. If it's not so prevalent, how many instances? Do we need to get a whole governmental bureaucracy set up? Excuse me. Let me tell you, I just came from the hearing on treatment of animals and I don't consider humans as animals, but we heard testimony from an executive with the National Institutes of Health and it was simply a paper facade that had been built with no substance. What I'm trying to suggest is maybe you're better off without that sort of thing where your own self interests are involved.

Mr. SAMUELS. Well, let me give you very briefly a case history of why we have these very high concerns and why you need governmental action. Without governmental action today in the lead industry, thousands of workers would be popping pills to remove lead. Now the reason they pop these pills—pills that are chelating agents—is because there's been some screening—not genetic screening. In this case, this was screening for the presence or absence of high levels of lead in the blood and sometimes in the urine. Lives have been destroyed. Workers have been unprotected. Workers' families have gone uncompensated, and so forth.

Based on that past history, we have a right to look at any screening with a rather jaundiced eye and we realize that just creating a governmental structure doesn't solve the problem, but what it does do, Mr. Shamansky, is create a structure within which we can accomplish a great deal.

Mr. SHAMANSKY. But are you suggesting that you cannot bargain to create your own private—you bargain for the other terms of your contracts. Why can't you bargain for this one?

Mr. SAMUELS. I think that there's a misunderstanding about the ability to deal with problems at the bargaining table. For example, we have been relatively successful in the economic areas.

Mr. SHAMANSKY. Have you tried these other ones?

Mr. SAMUELS. Let me explain what I'm trying to say. Would we have been successful in these economic areas without a minimum wage, with the rights to have unions and so on? Obviously, we need governmental intervention to successfully bargain in this area.

Mr. SHAMANSKY. You can't bargain otherwise?

Mr. SAMUELS. We can't have a union without governmental intervention.

Mr. SHAMANSKY. Excuse me, gentlemen. You heard a bell ring. That's my electronic tether pulling me to the floor of the House of Representatives for a vote. We will adjourn for about 10 or 15 minutes.

[Recess.]

Mr. GORE. The subcommittee will come back to order.

I'd like to apologize to all of our witnesses. This is a most unusual day, more unusual than usual, if you know what I mean. We've got the AWACS controversy on the floor involving the executive branch and the legislative branch and down the hall Secretary James Watt is about to be cited for contempt of Congress, a subhistoric occasion but one which nevertheless requires some careful attention. So I apologize and ask the patience and indulgence of our witnesses.

I agree with you, Mr. Samuels, this may well turn out to be the most important issue facing the work force in this coming decade. We have surveyed the potential for use of genetic screening techniques with HLA antigens and a variety of other descriptive markers, and the legal pressures which we will hear described in the case studies that we are about to turn to will also provide a great deal of pressure to use these new genetic screening techniques widely. There are already four laboratories here in the Washington, D.C. area that provide HLA antigen analysis and I'm quite concerned that the legal and ethical problems that we have seen appear in their initial form with respect to health screening are going to become much, much larger issues, and they are not easy issues by any means. It's going to be difficult for our society to deal with them, but you all have helped us tremendously in getting started in that regard.

I'd like to recognize my colleague, Mr. Walker.

Mr. WALKER. I have no questions.

Mr. GORE. I'm advised that my colleagues have asked a number of the questions that I had intended to ask. With that, I'd like to again express our thanks to you for getting us started in this endeavor. Thank you very, very much.

I'd like to call our second panel: Dr. Max Rogers, the medical director for the Southern Railroad; and Dr. John Meyers, medical director for the Southern Pacific Railroad; and ask them to come forward to the witness table.

Without objection, we will put the prepared statements of both of our next witnesses into the record at this point. I'd like to welcome you, Dr. Rogers and Dr. Myers, and, Dr. Rogers, you're accompanied by counsel; is that correct?

Dr. ROGERS. That is correct.

Mr. GORE. Could you identify yourselves for the record?

Mr. MITCHELL. My name is Wiley Mitchell. I'm general solicitor for the Southern Railway.

Mr. GRANUM. And I'm Jim Granum, special representative for Government Affairs with the Southern Railway Co.

Mr. GORE. I would like to welcome you also and I assume you're appearing here as counsel for the witnesses?

Mr. MITCHELL. That's correct.

Mr. GORE. Without objection, as I said, both of your statements will be put into the record in full at this point and we would invite you to proceed with the presentation of all of the statement or a summary if you wish and, Dr. Rogers, we will begin with you.

STATEMENT OF MAX ROGERS, CHIEF SURGEON, SOUTHERN RAILWAY CO., ACCOMPANIED BY WILEY MITCHELL, GENERAL SOLICITOR, AND JAMES GRANUM, SPECIAL REPRESENTATIVE FOR GOVERNMENT AFFAIRS, SOUTHERN RAILWAY CO.

Dr. ROGERS. Thank you, Mr. Chairman. I am Dr. Max P. Rogers, chief surgeon, Southern Railway Co.

I am a medical doctor, a graduate of Duke University School of Medicine. After my internship and residency at Duke, I was in the private practice of surgery for 20 years before joining Southern as chief surgeon in 1966. In that capacity, I am responsible for overseeing the medical programs for more than 21,000 persons employed by the railroad.

Southern operates about 10,500 route-miles of line in 13 States in the Southeast and Midwest. Currently Southern moves about 650 freight trains per day. Railroad work in running trains and building and repairing equipment and structures is hard, physical work, and it is dangerous unless safe work practices are followed by physically and mentally fit employees. Out on the line and in yards and shops heavy equipment must be used in all kinds of weather. Because of the nature of railroad operations, all railroads are very safety conscious. Southern has been a leader in the field of safety. In recent years we have received Harriman awards, trophies given to the railroads with the best safety records.

The safety consciousness at Southern begins with the hiring of a new employee. Over the years we have developed employee recruiting and selection programs designed to attract and hire those persons who are physically able safely to perform the jobs for which they are hired. The more strenuous the job, the more physically fit an employee must be. A clerical worker, for example, need not have the same abilities as a trainman, whose work involves jumping on and off moving trains and lifting and carrying heavy objects.

Mr. Chairman, in order to illustrate the strenuous nature of railroad employment I would like to submit for the record a pamphlet we have prepared at Southern outlining "Safe Work Practices for Railroad Employees." Safety awareness is an ongoing program at our railroad in order to minimize injuries for our employ-

ees. Railroad employees must be physically fit and mentally alert at all times in order to avoid an injury to themselves or fellow workers.

Our responsibility as an employer extends from hiring the right employee to work the right job to the maintenance of a continuing program of education in order to achieve safety awareness among all employees.

At the hiring stage Southern performs a preemployment physical examination of every applicant who has passed the employment interview. This includes a medical history, physical examination and, in those positions involving substantial physical exertion, the back X-ray. The little booklet on "Safe Work Practices for Railroad Employees" contains photographs showing good safety practices. Those illustrations demonstrate the amount of physical exertion and coordination which is an essential part of safe railroad operations. Moving trains, switching trains, repairing track and other rail structures is hard physical labor. In spite of our best efforts, some employees are injured in performing those tasks. To the extent that we can hire the right person for the right job, we reduce the likelihood that an individual will be physically harmed in performing his job. To the extent that we are successful in teaching all employees safe methods for doing their jobs, we prevent injuries to individuals.

In the late 1960's we began the use of back X-rays as a tool to aid in screening out those employees who had bad backs or backs which would be susceptible to future injury if subjected to the strenuous physical exertion necessary to many railroad jobs. For the record, I have attached to my prepared statement, Mr. Chairman, the pertinent part of a paper I presented in 1973 to the "Conference on Low Back X-Rays in Preemployment Physical Examinations", sponsored by the American College of Radiology, The American Academy of Orthopedic Surgeons, and the Industrial Medicine Association, under the further sponsorship of NIOSH, explaining our use of the back X-ray as a tool for identifying individuals who would risk injury at a greater rate than normal if employed in certain jobs on the railroad.

I would like to add at this point that the figures given in that paper were those of 1971 and they are understated in terms of present day figures. For example, in 1971, I quoted that the average cost of settling a case of a ruptured intervertebral disc was \$32,000. At the present date, 1980-81, this figure is now in the realm of \$125,000 to \$150,000 and sometimes higher in injury awards.

Unfortunately, the back X-ray is not a perfect measurement for predicting the likelihood of future back injuries. And, I am aware of the disagreement in medical circles about the level of predictability of back injuries that the back X-ray affords. However, when used in conjunction with a physical examination and a complete medical history of an applicant, it is my medical judgment that it provides a good indicator that certain individuals would be exposed to unacceptable levels of risk if they were hired to do certain strenuous jobs on the railroad. Certainly, if intelligently applied, it is a far better predictor than any other test I know of—and it is assuredly better than no screening at all.

I might add, Mr. Chairman, that sometimes an applicant with a congenital back defect learns of his problem only as a result of the back X-ray we have required. For example, the 19-, 20-, or 21-year-old individual with a congenital back defect has not yet begun to experience the degenerative process of aging which would eventually allow the congenital defect to be the cause of marked disability. It is important to discover these congenital difficulties and advise an applicant as to how to take precautions to minimize the risk of future injury in bending, lifting, stooping, or other activities. In such cases, the back X-ray often results in steering an individual to a career, in or out of the railroad industry, where physical demands are less stringent than those in railroad train and engine service, shop jobs, or track or signal construction or repair jobs. Such individuals often change their physical activities outside of the workplace and thereby prevent the onset of a back disability. For some individuals, for example, this may mean substituting fishing for weightlifting or hiking for wrestling.

Railroads such as Southern did not begin the use of back X-rays as a preemployment screen simply on a whim. It was done following years of injury experience in the railroad industry, where even employees following safe practices would suffer back injuries or pain. The human back is always subject to injury when it is misused. The unhealthy human back can be injured when an individual is lifting or otherwise physically exerting himself or herself in a safe manner. All too often, no amount of education or training can prevent the individual with a back predisposed to injury from incurring further injury when he or she undertakes a work task which would carry only a slight risk or none for an individual with a healthy back.

Recognition of this fact led me and many other railway physicians to urge management not to place employees with back impairments in jobs which would require strenuous physical exertion which would be likely to result in a back injury. As businessmen rightfully concerned with the health of employees and the cost of employee injuries my management accepted the need for preemployment screening for physically impaired backs. Personal injury claims represent a substantial cost for any railroad. At Southern, in 1980, \$13,539,507 was paid in settlement of employee personal injury claims. In the railroad industry as a whole, more than \$343 million was paid for personal injury claims in 1980. On Southern, about 20 to 25 percent of such claims are for back injuries.

The use of back X-rays as one tool for determining whether an individual should be hired for a job requiring strenuous physical exertion in the railroad industry is justified not only because of the nature of some railroad jobs but also based upon the injury experience within the railroad industry. Utilization by Southern of medical histories and physical examinations in conjunction with low-back X-rays, in my judgment, has protected hundreds of individuals from being placed in jobs which they are not physically capable of safely performing. I believe that employers must be given wide latitude in using predictive devices such as back X-rays to screen employment applicants where jobs are dangerous or strenuous, and the health and safety of the potential employee, other

employees, and the public are at risk, as is the case in hiring for railroad jobs.

Screening applicants for jobs on the basis of medical evidence does not involve just the use of the back X-ray. For example, in our industry we rely heavily on color signals in the operation of our trains. Therefore, it is essential that employees involved in the operation of trains should have good color vision. The tests we use are considered to be the best available to determine if an individual's color vision is safe or unsafe. For both the safety of the individual and the safety of other employees we cannot permit an individual who is color unsafe to operate our trains. It has been my experience that there is less criticism of this particular screening tool because of the absolute predictability of color deficiency for those who fail the test. Unfortunately, the degree of predictability for determining back injuries from the use of a medical history, a medical examination, and back X-rays is less perfect. Nevertheless, it is the best available means for making such a determination and I for one do not want to risk the safety of our employees and the public by forgoing medical screening of job applicants until it is as reliable as the test for determining if an individual is color safe.

The science of medicine is advancing by leaps and bounds. I suppose we now know at least twice as much about the human body and disease as we did when I was in medical school. I hope that medical science will develop foolproof systems for predicting which of us will have a particular susceptibility to particular injuries or diseases. Someday genetic screening may be of great value in preemployment selection. But that day is not yet, and Southern therefore does not use genetic screening. When the day comes I think that employees, employers, and society in general will want to minimize the risk to the individual by using such tools to place individuals in occupations where they will not be working at an unacceptable level of risk.

In your letter inviting me to testify one of the questions raised was, "Can or should the workplace be altered to eliminate the risk to these high risk groups?" In the railroad industry we are always striving to improve the workplace to eliminate the risk of accident and injury, but it is unlikely perfect safety could ever be achieved in that way. One limiting factor in safety in my industry is the safety awareness of our employees. Training to inculcate that awareness is the most important means for reducing accidents and injuries. Southern and other railroads are constantly reviewing and changing their practices, procedures, and physical plants in order to minimize the likelihood of accidents. That will continue, but in the final analysis accident prevention through constant safety awareness by employees is the best remedy.

Another question raised in the letter inviting me to testify was whether workers should be permitted to assume the risk involved in a particular job. As you know, Mr. Chairman, in the railroad industry the Federal Employers Liability Act precludes employees assuming the risk even if it were good public policy for them to do so. As a doctor, I am opposed to putting a man or a woman in a job that he or she cannot physically do without running a substantial risk of physical injury.

In conclusion, Mr. Chairman, I believe that employers should use back X-ray screening as a tool for putting an individual in a job that he or she can safely perform. Accident prevention is the best means for avoiding injuries. In my judgment, accident prevention begins in the hiring process and continues every day that an employee works for the company. There are thousands of jobs in our society and within the railroad industry. The goal of all concerned should be to place men and women in jobs for which they are qualified physically and mentally and in which they will not unnecessarily risk their lives or limbs or the safety of the public.

Thank you.

[The prepared statement of Dr. Rogers follows:]

PREPARED STATEMENT OF DR. MAX P. ROGERS

Mr. Chairman, I appreciate the opportunity to be heard today. I am Dr. Max P. Rogers, Chief Surgeon, Southern Railway Company. With me today are Wiley Mitchell, General Solicitor and James Granum, Special Representative for Government Affairs, all with Southern Railway Company.

I am a medical doctor, a graduate of Duke University School of Medicine. After my internship and residency at Duke, I was in the private practice of surgery for 20 years before joining Southern as Chief Surgeon, in 1966. In that capacity, I am responsible for overseeing the medical programs for more than 21,000 persons employed by the railroad.

Southern operates about 10,500 route miles of line in 13 states in the Southeast and Midwest. Currently Southern moves about 650 freight trains per day. Railroad work in running trains and building and repairing equipment and structures is hard, physical work, and it is dangerous unless safe work practices are followed by physically and mentally fit employees. Out on the line and in yards and shops heavy equipment must be used in all kinds of weather. Because of the nature of railroad operations, all railroads are very safety conscious. Southern has been a leader in the field of safety. In recent years we have received Harriman Awards, trophies given to the railroads with the best safety records.

The safety consciousness at Southern begins with the hiring of a new employee. Over the years we have developed employee recruiting and selection programs designed to attract and hire those persons who are physically able safely to perform the jobs for which they are hired. The more strenuous the job the more physically fit an employee must be. A clerical worker, for example, need not have the same abilities as a trainman, whose work involves jumping on and off moving trains and lifting and carrying heavy objects.

Mr. Chairman, in order to illustrate the strenuous nature of railroad employment I would like to submit for the record a pamphlet we have prepared at Southern outlining "Safe Work Practices for Railroad Employees." Safety awareness is an ongoing program at our railroad in order to minimize injuries for our employees. Railroad employees must be physically fit and mentally alert at all times in order to avoid an injury to themselves or fellow workers.

Our responsibility as an employer extends from hiring the right employee to work the right job to the maintenance of a continuing program of education in order to achieve safety awareness among all employees.

At the hiring stage Southern performs a preemployment physical examination of every applicant who has passed the employment interview. This includes a medical history, physical examination and, in those positions involving substantial physical exertion, the back X-ray. The little booklet on "Safe Work Practices for Railroad Employees" contains photographs showing good safety practices. Those illustrations demonstrate the amount of physical exertion and coordination which is an essential part of safe railroad operations. Moving trains, switching trains, repairing track and other rail structures is hard physical labor. In spite of our best efforts, some employees are injured in performing those tasks. To the extent that we can hire the right person for the right job, we reduce the likelihood that an individual will be physically harmed in performing his job. To the extent that we are successful in teaching all employees safe methods for doing their jobs, we prevent injuries to individuals.

In the late 1960's we began the use of back X-rays as a tool to aid in screening out those employees who had bad backs or backs which would be susceptible to future injury if subjected to the strenuous physical exertion necessary to many railroad

jobs. For the record I have attached to my prepared statement, Mr. Chairman, the pertinent part of a paper I presented in 1973 to the Conference on Low Back X-rays in Preemployment Physical Examinations, sponsored by the American College of Radiology, The American Academy of Orthopaedic Surgeons, and the Industrial Medicine Association, under the further sponsorship of NIOSH, explaining our use of the back X-ray as a tool for identifying individuals who would risk injury at a greater rate than normal if employed in certain jobs on the railroad.

Unfortunately, the back X-ray is not a perfect measurement for predicting the likelihood of future back injuries. And, I am aware of the disagreement in medical circles about the level of predictability of back injuries that the back X-ray affords. However, when used in conjunction with a physical examination and a complete medical history of an applicant, it is my medical judgment that it provides a good indicator that certain individuals would be exposed to unacceptable levels of risk if they were hired to do certain strenuous jobs on the railroad. Certainly, if intelligently applied, it is a far better predictor than any other test I know of—and it is assuredly better than no screening at all.

I might add, Mr. Chairman, that sometimes an applicant with a congenital back defect learns of his problem only as a result of the back X-ray we have required. For example, the 19, 20, or 21-year-old individual with a congenital back defect has not yet begun to experience the degenerative process of aging which would eventually allow the congenital defect to be the cause of marked disability. It is important to discover these congenital difficulties and advise an applicant as to how to take precautions to minimize the risk of future injury in bending, lifting, stooping or other activities. In such cases the back X-ray often results in steering an individual to a career, in or out of the railroad industry, where physical demands are less stringent than those in railroad train and engine service, shop jobs, or track or signal construction or repair jobs. Such individuals often change their physical activities outside of the work place and thereby prevent the onset of a back disability. For some individuals, for example, this may mean substituting fishing for weightlifting or hiking for wrestling.

Railroads such as Southern did not begin the use of back X-rays as a preemployment screen simply on a whim. It was done following years of injury experience in the railroad industry, where even employees following safe practices would suffer back injuries or pain. The human back is always subject to injury when it is misused. The unhealthy human back can be injured when an individual is lifting or otherwise physically exerting himself or herself in a safe manner. All too often, no amount of education or training can prevent the individual with a back predisposed to injury from incurring further injury when he or she undertakes a work task which would carry only a slight risk or none for an individual with a healthy back.

Recognition of this fact led me and many other railway physicians to urge management not to place employees with back impairments in jobs which would require strenuous physical exertion which would be likely to result in a back injury. As businessmen rightfully concerned with the health of employees and the cost of employee injuries my management accepted the need for preemployment screening for physically impaired backs. Personal injury claims represent a substantial cost for any railroad. At Southern in 1980 \$13,539,507 was paid in settlement of employee personal injury claims. In the railroad industry as a whole more than \$343,000,000 was paid for personal injury claims in 1980. On Southern about 20 to 25 percent of such claims are for back injuries.

The use of back X-rays as one tool for determining whether an individual should be hired for a job requiring strenuous physical exertion in the railroad industry is justified not only because of the nature of some railroad jobs but also based upon the injury experience within the railroad industry. Utilization by Southern of medical histories and physical examinations in conjunction with low back X-rays, in my judgment, has protected hundreds of individuals from being placed in jobs which they are not physically capable of safely performing. I believe that employers must be given wide latitude in using predictive devices such as back X-rays to screen employment applicants where jobs are dangerous or strenuous, and the health and safety of the potential employee, other employees, and the public are at risk, as is the case in hiring for railroad jobs.

Screening applicants for jobs on the basis of medical evidence does not involve just the use of the back X-ray. For example, in our industry we rely heavily on color signals in the operation of our trains. Therefore, it is essential that employees involved in the operation of trains should have good color vision. The tests we use are considered to be the best available to determine if an individual's color vision is safe or unsafe. For both the safety of the individual and the safety of other employees we cannot permit an individual who is color unsafe to operate our trains. It has been my experience that there is less criticism of this particular screening

tool because of the absolute predictability of color deficiency for those who fail the test. Unfortunately, the degree of predictability for determining back injuries from the use of a medical history, a medical examination, and back X-rays is less perfect. Nevertheless it is the best available means for making such a determination and I for one do not want to risk the safety of our employees and the public by foregoing medical screening of job applicants until it is as reliable as the test for determining if an individual is color safe.

The science of medicine is advancing by leaps and bounds. I suppose we now know at least twice as much about the human body and disease as we did when I was in medical school. I hope that medical science will develop foolproof systems for predicting which of us will have a particular susceptibility to particular injuries or diseases. Some day genetic screening may be of great value in preemployment selection. But that day is not yet, and Southern therefore does not use genetic screening. When the day comes I think that employees, employers and society in general will want to minimize the risk to the individual by using such tools to place individuals in occupations where they will not be working at an unacceptable level of risk.

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In conclusion, Mr. Chairman, I believe that employers should use back X-ray screening as a tool for putting an individual in a job that he or she can safely perform. Accident prevention is the best means for avoiding injuries. In my judgment accident prevention begins in the hiring process and continues every day that an employee works for the company. There are thousands of jobs in our society and within the railroad industry. The goal of all concerned should be to place men and women in jobs for which they are qualified physically and mentally and in which they will not unnecessarily risk their lives or limbs or the safety of the public.

ADDENDUM

I have just completed perusing a total of 795 back cases which occurred on American railroads during the year 1971. There exists in the set-up of the Association of American Railroads what is known as a Claims Index Bureau. Out of the 90-95 railroads in this country, approximately 60-70 of these railroads regularly report all of their personal injury claims to this Index Bureau. Records are kept of these claims for the purpose of analysis of trends, costs and so forth. I was furnished records of all of the back cases which were reported to this bureau in 1971. These totalled 795 cases. This total was further broken down into 292 cases of ruptured intervertebral discs, 57 cases of cervical injuries and all other back cases total 445. This immediately points out a rather interesting finding that of all of the back injury cases reported to the bureau during 1971, almost 40 percent of those cases were those involving a ruptured intervertebral disc. Now, let us take a look at these 795 cases as to what these cases cost the carrier in terms of settlement. The total cost of these 795 back cases was \$18,515,539. This is a staggering figure. Further, to break this down, it is shown that the disc cases cost a total of \$9,494,089. The cervical injury cases cost \$858,045. All of the other back cases cost a total of \$8,163,405.

Then, to pursue this analysis just a little bit more, it is shown that the average of the ordinary back case, excluding the disc cases, was \$17,971 per case in settlement. These cases were reported in the majority as being cases purely and simply of strain. On the other hand, the average cost per case to settle the employee with a ruptured intervertebral disc was \$32,403. Therefore, it can be seen that it costs

twice as much to settle a back injury case if a disc is involved than if it is an ordinary back injury.

I then attempted to take a look at some other interesting reports that could be derived from this inasmuch as in my particular company, in 1968, I included X-rays of the cervical spine as part of my routine, pre-employment back X-ray program. My total pre-employment back X-ray involves an AP and lateral of the cervical spine and an AP and lateral and 45 degree obliques of the lumbosacral spine. Therefore, I took a careful look at 57 cases of cervical injuries reported in this group. The age range in this group varied from 21-49 years of age with an average of 35 years. All of these cases were listed as so-called whiplash injuries or cervical strain. These 57 cases averaged \$15,053 to settle each case. Now, to my knowledge, our company is the only railroad doing cervical X-rays. In 1971, I had no claims for cervical injuries. This raises the question, relating to a statement which has been frequently found in the literature, that a whiplash injury does not occur unless there is an abnormal cervical spine to begin with. Therefore, could these 57 cases have saved American railroads \$858,000 had they been excluded from employment by pre-employment cervical X-rays?

I also took a look at 151 cases of back injuries all under 50 years of age which did not include any fractures or blow to the back resulting in direct damage to the bone but consisted mainly of diagnoses of spondylolisthesis, degenerative disease, spondylitis, spondylolysis or conditions which I felt could probably have been excluded by proper pre-employment back X-rays. In this group of 151 cases, the average age was 31 years and the total cost of this particular group was \$2,153,686 with an average cost per case of \$14,262.

Now, concerning my statement regarding the so-called case of strain, I would like to say that I am extremely interested and feel there is a direct relationship between an increased lumbosacral angle and the occurrence of disability and back strain as a result of heavy lifting or strenuous work. In fact, it is requested of all the radiologists who do pre-employment X-rays for the Southern Railway System that the lumbosacral angle be reported and measured according to the technique of Ferguson. In this regard, if a lumbosacral angle is above 45 degrees, it is considered to be disqualifying. I have discussed this problem with many radiologists and orthopedists and it is definitely the feeling of most of the ones that I have talked to that when the lumbosacral angle is increased above 45 degrees, when the line of weight bearing falls far enough anterior, there is definitely an increase in the shearing force at L-5 and sacrum. In our particular industry, we have a large number of employees who are involved in jumping on and off moving trains constantly. When a man is riding the footboard of an engine and while it is moving, jumps off to the ground in a running position, he certainly is jolting and straining his lumbar spine considerably and, if the angle is markedly increased, or if there is a pars defect or spondylolisthesis or spondylolysis, I certainly think that he is headed for trouble. Therefore, I think it is important that we exclude these people from employment by means of pre-employment X-rays.

But to get into the financial side of this picture, a little bit more, investigational claim records also reveal that in 1972, there were 93 cases which required settlements of over \$100,000. This ranged all the way from \$100,000 to \$900,000 but there were 93 cases over \$100,000 settlements. In addition to this, it has also been shown from the record that in the last three months of 1972, there were three cases in which the judgment was \$100,000,000 or above.

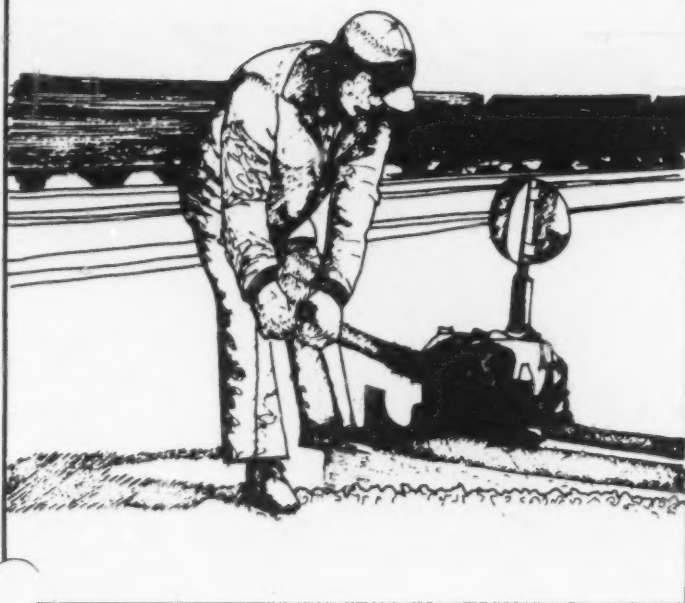
To bring these figures a little closer to home, our own statistics show that during the year 1971, the year in which I reported a pay-out for the country as a whole by railroads of \$18,000,000, my company alone spent \$507,484 in settling back injury cases. Now, what can we prove from this? In the year prior to the institution of the back X-ray program within my company, back claims cost us a little over \$300,000 in comparison with back injuries in 1971 costing \$500,000. However, when one considers the marked escalation of jury verdicts, the escalation in salaries, medical costs, etc., I would certainly expect that we could have realistically expected a pay-out of triple the amount paid out in the year before the X-ray program was begun. After all, one would only have to have five cases with settlements of \$100,000 apiece to equal the amount that we paid out for back claims in 1971. Without a pre-employment back X-ray program, it would be my estimate that back injuries would have cost us between \$900,000 and \$1,000,000 in 1971. However, our payout was only \$500,000. In addition to this, my claim department advises me that the total number of claims for back injuries is decreasing, although the individual cost of each case is increasing.

Now, let us turn to another interesting aspect of this situation. 1971 was a big year for employment with the Southern Railway System. During that year, I processed a little over 5800 applicant files. Of that total number of applicants, approxi-

mately 90 percent of them received pre-employment back X-rays. Since my average cost for pre-employment back X-rays is in the neighborhood of \$45, it is my estimate that, in 1971, I vouchered approximately \$200,000 for pre-employment back X-rays. At first glance, this seems to be an enormous figure. However, when one takes into consideration the number of applicants processed and takes into consideration the average cost of settling a disc case, my total X-ray costs would be paid for if I could have saved six disc cases from employment. On the other hand, the total cost of X-rays could be borne by saving 12 non-disc cases from employment. Actually, the only conclusion that we can draw is that all of the X-rays could be paid for by just a very few expensive case settlements.

I have shown in these few minutes the problem which we are faced with in my particular industry. We are governed by federal statutes under which liability is almost absolute in every case and which allows for recovery on the part of the plaintiff with the sky as the limit with practically no defense whatsoever. I thoroughly realize that by means of a pre-employment back X-ray that we cannot possibly exclude from employment all of the potential back injury cases, nor am I naive enough to believe that we can accurately predict by a pre-employment X-ray all of the back injuries that will occur inasmuch as we know that there are people with spondylolisthesis, for instance, who go through life in a heavy industry and never have one minute's trouble and then there are those who suffer disabling back injuries with a perfectly normal back X-ray. On the other hand, there are those conditions which, although they may not be 100 percent in every case, we know are certainly apt to make an individual more prone toward a particular back injury.

**SAFE WORK PRACTICES
FOR
RAILROAD EMPLOYEES**



FOREWARD

This is a handbook of safety suggestions designed to assist in the prevention of the most common types of injuries to employees in road and yard service and other employees in Operations.

SAFETY GOES MUCH FURTHER THAN
RULES AND THEIR ENFORCEMENT.
IT INVOLVES THE CULTIVATION
OF SAFE HABITS AND THE
DEVELOPMENT OF RESTRAINT
AND SELF-CONTROL.



Know the requirements of your job, plan the work immediately ahead and keep your mind on it while you are doing it.

DRESS FOR SAFETY

- ...Wear hat or cap to protect your head and eyes. Head coverings should not obstruct hearing or sight.
- ...Clothing should fit well so as not to catch on equipment.
- ...Wear gloves to protect your hands.
- ...Keep pockets free of cumbersome objects.
- ...Wear ankle high laceup shoes to protect feet and support ankles. Safety shoes are recommended.

Appearance and safe dress indicate pride, alertness on the job and provide a good example for others.



COUPLING OR UNCOUPLING LOCOMOTIVES AND CARS

Don't Go Between Moving Equipment



Do not go between a locomotive and a car or between cars for any purpose when either is moving toward the other and coupling is about to be made.

The proper time to adjust couplers is when the equipment is stopped and the distance between couplers is at least 20 feet.

There must be complete understanding between members of the crew as to the movements to be made. With the equipment standing, adjust the coupler if necessary, if difficult request assistance, then move to a place of safety, and proceed with the job.

Adjusting the Coupler



When adjusting the coupler on a standing car be alert to possible movement of other equipment.

Before opening knuckles ascertain that knuckle pins are in place.

Employee should provide protection for himself by verbal communication with the engineman, or by signal and acknowledgement.

Operating the Uncoupling Lever



The proper way to operate the uncoupling lever on moving equipment is to face the direction of movement, and watch your footing.

If it fails to work, stop the movement and have proper understanding before operating uncoupling lever on the opposite side.

If necessary to ride car when operating a cut lever, only operate lever on car which is being ridden. Do not reach from one car to another.

Handling Air Hoses



There is no danger in handling air hoses if the following practices are adopted:

Before coupling hoses, always close the angle cocks to shut off the air pressure.

When coupling hoses, always be sure the glad hands are properly engaged before opening angle cocks.

When opening angle cock by hand on uncoupled hose, have a firm grip on air hose or keep clear of flying hose.

Never attempt to adjust glad hands to stop a leak without closing both angle cocks.

When uncoupling air hose by hand, close both angle cocks, firmly grip each hose just above the glad hand, partly open joint to release air pressure and then raise joint until it separates.

OPERATING LOCOMOTIVES

The following practical suggestions indicate how employees called upon to work on or about locomotives can avoid injury.

The entire crew should be familiar with and know the location of all fire extinguishers and fuel cut-offs on diesel locomotives.

Metal cased flashlights should never be used around electrical equipment. Hard rubber or any non-metallic cased flashlight should be used.

No work should be performed on any electrical equipment while wearing a ring or a wristwatch. Either of them could come in contact with electrical equipment and cause a severe burn.

When starting a diesel engine, know that all workmen have been notified and are in a safe position.

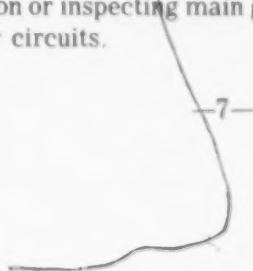
On any unattended diesel locomotive, the generator field switch should be pulled out and the independent air brake and hand brakes set. If possible, the reverse lever should be removed from the controller. Isolation switch should be turned to "Start" or "Off" position.

Keep all parts of body and clothing out of radiator shutters, heaters or any equipment which operates automatically.

High voltage cabinet should not be entered by Train and Engine Service employees under any circumstances.

Fuses in low voltage cabinet should not be pulled while they are under load or while diesel engine is running. Ground relay protective knife switch must not be opened to prevent repeated tripping of ground relay.

Generator field switch should be in "Off" position while working on or inspecting main generator, traction motors or power circuits.



Flagstaff or other object should not be used in closing or opening contacts on locomotives while under electrical load.

Loose cloths, rags or waste must not be left in the engineroom as there is danger of them being picked up by air currents and carried to the air filters, traction motors, or generator blowers.

Diesel locomotives should not be stopped over burning fusees, switch heaters or other open flames.

Do not blow down steam generator, or open train line shut-off valve at station platforms, while coupling or uncoupling units, over switches or through interlockers, or at any location where anyone may be injured.

Use door handle in opening and closing door. Do not use edge of door or place hand on door frame.

It is essential that the engineroom, cab, catwalks, steps and grab irons be kept free from oil, grease, rags and other objects at all times.

OPERATING HAND BRAKES

There are many different kinds of hand brakes, calling for different methods of operation. Any hand brake may be operated safely if handled properly. The following pages illustrate the proper method of going up or down ladders, reaching the brake platform, and operating the hand brake.

Going Up or Down Ladders

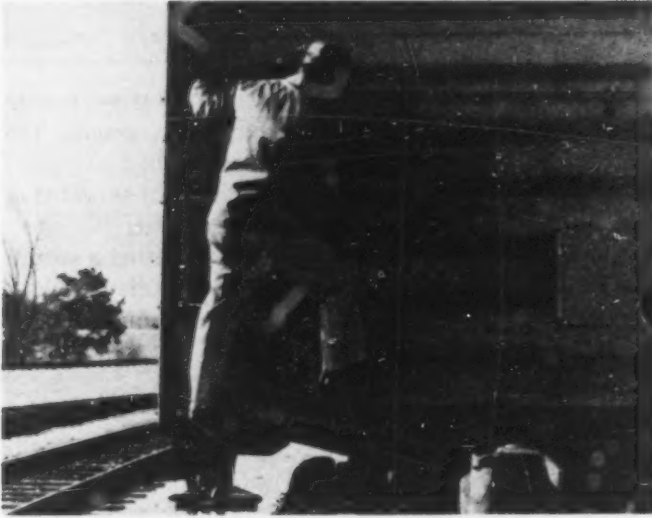
Maintain alertness when getting on or off cars. Grasp the rungs firmly. Turn the feet at an angle and place the ball of the foot on the ladder rung to improve footing and make it easier to climb. Use side ladder ascending or descending car. Never use end ladder.

When descending from a standing car be sure that your feet are firmly on the ground before releasing your grip on the grab iron. Always look for safe footing before dismounting from either moving or standing equipment.

When getting off moving equipment, face the direction of movement, and be certain to keep clear of adjacent tracks, and obstructions. Check for good footing and maintain hand hold until feet are on ground.



Operating Vertical or Power Brake Wheel



In moving to the brake platform, keep yourself well braced against sudden movement; maintain firm handhold and foothold at all times.

The operator should place right foot on brake platform, with heel locked against end of platform (as shown in above photograph), left foot on end ladder rung or grab iron. With right hand remove or release lever to extreme left or "ON" position, and with right hand turn the wheel clockwise until slack is taken up and braking pressure secured. Always maintain a firm grip on the grab iron with the left hand.

When applying hand brake always grasp the rim of the wheel for maximum leverage. Never reach through the spokes of a brake wheel as wheel may spin. Keep hands and fingers in the clear of wheel when releasing wheel-type hand brake.

OPERATING SWITCHES

Injuries are unnecessary if switches are operated properly.

By far the great majority of injuries in this work area are caused by failure of the employee to assume the proper position and to follow the safe method.

Look for out-of-service tags. When an out-of-service tag is on the switch, never attempt to operate it.

When difficulty is experienced while operating a switch it should be promptly reported to proper authority.

The following pages outline several methods of operating switches.

**Think About What You're Doing When
Operating Switches**



To operate a switch face the stand with feet firmly placed, and keep your body and feet clear of moving parts.

In the operation of a high switch stand, pull the lever to you instead of shoving it away from you.



To avoid strains and sprains acquire and maintain the habit of using leg muscles when lifting.

Use handle of broom if available or a similar object to clear foreign matter out of switch points.

Check the point for proper fit after the switch has been thrown.

GETTING ON OR OFF LOCOMOTIVES OR CARS

With many kinds of equipment, each with its own particular appurtenances, it is impossible to treat here any but those most generally in use, and yet the same principles illustrated and described on the following pages apply in all cases.

When getting on or off equipment, the employee should ascertain that speed and ground conditions are such that it can be done with safety.

Enginemen, pulling out of yards or side tracks, might well put themselves in the other fellow's place and regulate speed accordingly.

The succeeding pages show the proper method of getting on and off equipment safely. Be alert to the work at hand, maintain a firm grasp and a safe foothold.

Slippery conditions underfoot call for special care.

Getting On Moving Caboose



Use rear steps and never attempt to get on with any object in the hands except a lantern. Travel bags and similar items should be placed on the leading platform and employee should board the trailing platform.

Be sure there are no switch stands or other obstructions in the way.

Gloves and footwear should be in good condition. Extra caution is necessary when they are wet or slippery.

Do not attempt to get on if speed is too great. In pulling out of yards and sidings, enginemen should regulate speed to permit employees to board safely consistent with existing conditions.

Getting Off Moving Caboose

The employee shown above is getting off the caboose in the right manner and, if the speed is not too great, will do so safely.

In getting off a moving caboose, face the equipment and look in the direction of movement, with both hands firmly grasping the grab irons. Be alert to obtain the best possible footing.

Getting On Moving Freight Car

A safe habit to form is to get ON cars after they pass switch stands or other obstructions. Board the leading end of cars except the last one in a cut to avoid the danger of being dragged from or thrown between the cars.

Getting Off Moving Freight Car

Get OFF a moving car after passing a switch stand or other side obstruction. Be alert for safe footing and movements on adjacent tracks. Step down with trailing foot which will brace you and impel you away from the car.

Getting Off Locomotive at Steps

Employees should face the steps, look both ways for movement on adjacent track as well as down to be sure of safe footing. Grasp the grab irons firmly and avoid carrying any objects other than a lantern or radio.

Getting On or Off Standing Equipment

Be alert at all times.

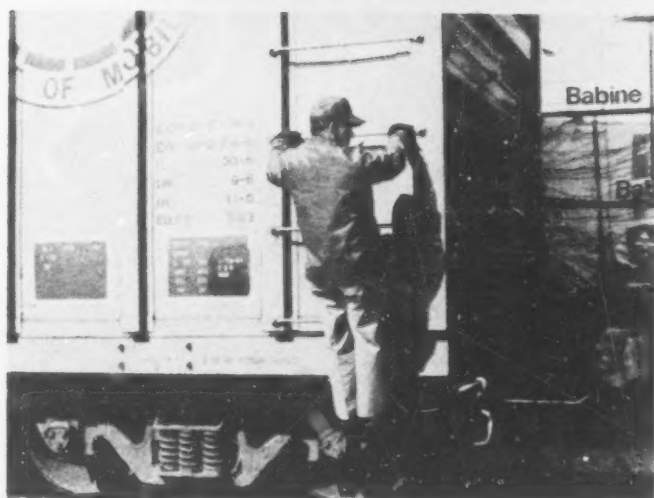
When getting on a standing car, grasp the rungs firmly. Turn the foot at an angle and place the ball of the foot on the ladder rung to improve footing and to make it easier to climb.

When getting off standing car, be sure your feet are firmly on the ground before releasing your grip on the grab irons. Look in both directions and be sure you do not foul equipment on adjacent track.

MISCELLANEOUS

Besides those causes of accidents and injuries which have already been discussed, there are numerous other ways in which a man can be hurt if he does not follow the safe course. The following pages illustrate a few of them.

These and the other potential causes of accidents can be avoided if you will think what you are doing when you are doing it; be sure of a firm grip and a safe foothold, and always look both ways.

Be Alert for Slack

Whether riding in locomotives, in cabooses or on the side of cars always stay alert to the possibility of slack running in or out. Brace yourself and keep a firm hand hold and secure footing. Occupants of cabooses are to be seated at points where slack normally runs in or out and at all times when speed of train is TEN (10) MILES PER HOUR or less, except while:

- ...Getting off caboose or preparing to get off.
- ...Boarding caboose.
- ...Crossing from one side of caboose to the other to observe train.
- ...Catching train orders.
- ...Protecting shove movements.
- ...Complying with Rules 19 and 99.

In a shove movement, not involving caboose, ride the side ladder, lead end of the lead car. Face the direction of the movement and maintain a firm hand hold and secure footing. Be alert for slack at all times.

Fixed Structures at Side of Tracks

Keep a sharp lookout for close clearances.

Never ride on the side or end of moving equipment when moving adjacent to platform, building or close clearance structure or stand between moving equipment and adjacent platform, building or close clearance structure.

Crossing Tracks and Walking in Yards



When on or about tracks, all employees should keep a constant lookout for equipment moving in either direction on any track at any time, and for equipment on converging tracks.

Form the habit of always looking in both directions before you foul any track, even though you know there is no movement on the track.

Always stand in the clear and let the locomotive or car pass, then you can cross the track safely. Always allow at least 10 feet distance when crossing around the end of equipment.

Step over, not on, the rails.

Avoid walking in the gauge of the track.

Out of Danger

If you cultivate the habit of remaining off the track at all times, unless required to be there in the performance of duty, you will protect yourself against being struck or run over by locomotives or cars.

Under no circumstances should you do any work or commit any act on the track that can be performed clear of the track.

Crossing Over Between Cars



Don't cross over at all unless it is necessary in performance of duty.

Select a car with end platform and avoid putting feet in any position where they may be injured should either car move.

Always maintain a grip with at least one hand while on the car.

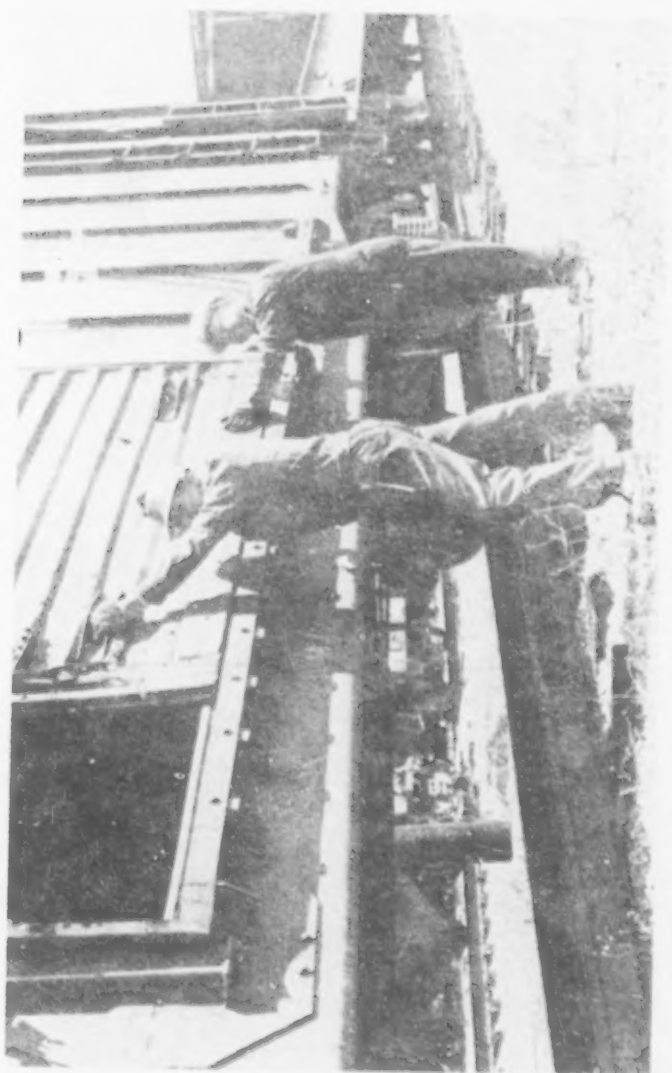
In getting down, check footing, use grab irons and stirrup and step to ground.

Opening and Closing Car Doors

If package freight is improperly stowed in the car, or handled roughly in transit, there is likelihood of it falling out of the door when it is opened.

Remember always to stand clear of the opening so that freight which might fall out cannot land on you.

Never attempt to open or close a car door that malfunctions due to damaged hardware, fittings, etc., as door may fall.



Mr. WALKER. Thank you very much for your testimony. I think what we'll do is go on and have the testimony of Dr. Myers and then I have questions for the panel Dr. Meyers.

[The biographical sketch of Dr. Meyers follows:]

CURRICULUM VITAE

JOHN E. MEYERS, M. D.

Personal Data: Address: Southern Pacific Building, Room 301
One Market Plaza, San Francisco, CA 94105

Born: March 24, 1929, Lehi, Utah

Education: Graduated Lehi High School - 1947
Graduated Brigham Young University - 1954
B. S. degree in Biochemistry
Graduated University of Utah School of Medicine - 1958
M. D. degree
Internship - 1958-59, Letterman Army Hospital, San Francisco
Graduated USAF School of Aviation Medicine - 1959
Occupational Medicine New York University - 1960
Treatment of Mass Casualties, Brooke Army Hospital - 1961
Medical Aspects of Nuclear Warfare, Sandia, New Mexico - 1961
Industrial Psychiatry, Mamminger Institute of Psych. - 1968
Passed written and oral exams for Board Certification in
Preventive and Occupational Medicine - 1969.

Military: Active Duty - 1959-64
1959-61 - Base Flight Surgeon, Turner Air Force Base, Georgia.
Responsible for all preventive, occupational and aviation problems.
1961-64 - Hospital Commander, Aviano AFB, Italy. Responsible for all medical problems for the American Air Force Base at Aviano and assigned to maintain close liaison with the medical community in Northern Italy.
1964-1980 - Air National Guard. Wing Surgeon 146th TAC Hospital.
1981 - Present - Wing Flight Surgeon, 349th MAW

Private Industry: 1964-67 - "Works Doctor". U.S. Steel Corporation, Provo, Utah
1967-68 - Medical Director, U. S. Steel Corporation, Fairless Hills, Pennsylvania
1968-73 - Medical Director, IBM Corporation, San Jose, California
1972-73 - President, Santa Clara County Chapter National Council of Alcoholism
1972-73 - Medical Director, Monte Villa Hospital Alcohol Program
1973- Present - Chief Medical Officer, Southern Pacific Transportation Company, San Francisco, California

State Medical Licenses Past and Present: California, Utah, Pennsylvania, New York

Achievements: 1969 - Designated as Diplomate in the American Board of Preventive and Occupational Medicine
 Past President of the San Francisco Peninsula Occupational Medical Society
 Currently "Associate" and Instructor in Occupational and Aviation Medicine of the University of California Medical School in San Francisco
 1964-67 - Chairman of the Occupational Medicine Committee, Utah County Medical Society
 1964-67 - Consultant for Occupational Medicine Department, Utah School of Medicine
 Recognized as Most Outstanding Intern, Letterman Army Hospital, San Francisco, 1958.
 Graduated with the highest academic class record, USAF School of Aviation Medicine - 1959.
 Completed two and one-half years assignment as a missionary for the Latter Day Saints Church in Australia - 1949-52
 Received University athletic letters in track, tennis and basketball - 1947-49 and 1952-54
 Undergraduate Instructor 1952-54, Brigham Young University in Chemistry
 Have commercial FAA license and fly actively for business and pleasure
 Currently designated as Class 1 FAA Medical Examiner

Associations and Memberships: American Medical Association
 California Medical Association
 San Francisco County Medical Society
 Industrial Medical Association
 American Association of Railway Surgeons

Community Work: On the Board of Directors for the Santa Clara County Rehabilitation Mental Health Services
 On the Board of Directors for the Santa Clara County Alcoholic Information Center
 Medical Consultant for "Pathway House", a community center for drug rehabilitation
 Past chairman, Occupational and Preventive Medical Section, California Medical Association

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**STATEMENT OF JOHN MEYERS, CHIEF MEDICAL OFFICER,
SOUTHERN PACIFIC TRANSPORTATION CO.**

Dr. MEYERS. Thank you, Mr. Chairman.

I am Dr. John Meyers. I am the chief medical officer for Southern Pacific Transportation Co. and my offices are located in San Francisco, Calif. I have attached to my statement a paper on my background. In summary, however, I am a graduate of the College of Medicine, University of Utah, and a specialist in preventative and occupational medicine. I have been involved in preventative medicine for the last 21 years, and have had the opportunity to work with various companies, including the U.S. Air Force, during that time. I am a graduate of the U.S. Air Force School of Aviation Medicine, and have worked for United States Steel Corp. for a period of 4 years; IBM for 5 years; and Southern Pacific Transportation Co. since 1973. I am still an active member of the U.S. Air Force Reserve, where I continue to practice preventative medicine. I have had extensive experience in heavy industry. I had my first job with the United States Steel Corp. at the age of 15. At the age of 18 I had my first job in the mines. Since that time I have worked in light and heavy industry before I came to work for the railroad. Since coming with the railroad, I find it is necessary to practice medicine in a far different manner, primarily because of the Federal Employers Liability Act, which is a Federal law governing railroad employers' obligations to its employees. Railroad workers, unlike those in virtually every other industry in the United States, are not governed by workman's compensation laws. They are governed by the Federal Employers Liability Act.

Under the Federal Employers Liability Act, a railroad employee cannot be assigned to a job if the individual creates a safety hazard to himself, fellow employees, or the public. Under FELA, an employee may file suit in either State or Federal court against the employer for injury incurred on the job.

The courts have liberally interpreted the requirement of the common carrier to provide a safe place to work. The Supreme Court of the United States has said that whenever a railroad employee under FELA is injured, and if there is any evidentiary basis upon which reasonable minds could believe that reasonable care might have required additional safety measures which were not taken, and which, in fact, contributed in whole or in part to cause the injury and/or death, the case should be submitted to the jury. The language of this decision then supports the proposition that there is an obligation on the part of the common carrier to anticipate and institute additional safety measures to make the place of work a safe one. The courts have also said the plaintiff, as

such, is not required to prove that the common carrier had actual or constructive notice as to the unsafe condition, and that this is a question for jury determination; and that presumption is that the employer has notice, since he controls the place of work and/or the assignments which the employee must carry out. For example, last year in Oakland, Calif., I released an employee with a history of emotional problems to return to work. Shortly after his return to work he shot a fellow employee. The employee who was shot sued the railroad under FELA law for not providing a safe place to work. This is the second such case I have experienced in Oakland in the past 2 years.

Our attorneys advise me that the court could instruct a jury that the plaintiff employee's burden of proof is to show that the cause of injury is one which in natural continuing sequence produced an injury and without which the injury would not have occurred. In other words, the jury need find only that the railroad's supposed negligence played some part in causing the plaintiff injuries. For example, if an employee with a known back condition were allowed to work in a job which was known to be excessive to his physical abilities and he injures himself, a causal relationship can be asserted by the plaintiff against the railroad. Failure to furnish adequate help has been held to be negligence under FELA. If an employee with a known medical condition such as degenerative arthritis in his back was assisting a fellow employee in lifting, and he dropped his share of the load and in turn caused injury to a fellow employee, it could be claimed that adequate help was not provided by the railroad.

Thus, liability can be claimed following injury upon evidence that the railroad negligently permits an employee known to be psychotic or known to have potential physical disabilities to work on the property, with the result being that said employee inflicted harm or injury to a coworker.

Liability can also be advanced on the theory that the carrier negligently permits an employee to return to duty knowing that the employee has a physical condition which renders him incapable of performing the work.

Under FELA, it is apparent that all applicants for employment in the railroad industry must be carefully screened to insure that they are at no greater risk than the average population for developing illness or injury in the course of their railroad employment.

As you can see, the rail industry has been singled out by Federal law because FELA supersedes the normal employer-employee relationship under workman's compensation statutes applicable to other industries.

Our attorneys advise me that FELA imposes an obligation on railroad employers to provide its employees a reasonably safe place to work. The act specifically provides, and various court interpretations have held, that contributory negligence and assumption of risk by the employee will not be a bar to recovery.

A court has found that "no employee shall be held to have assumed the risk of his employment in any case where the violation by any such common carrier of any statutes enacted for the safety of employees contributed to the injury or death of such employee."

As an example, last year I was personally sued as an officer of the company for malpractice because an employee with a back condition that I had released to return to duties on advice of his attending physician aggravated his back problem in the normal performance of his job.

The Office of Federal Contract Compliance Practice [OFCCP] has made the practice of railroad medicine even more difficult. The health and safety of individuals who may be injured as a result of action forced by the OFCCP was not anticipated by the FELA. The two are inconsistent and contradictory. The OFCCP has taken the position that anyone who is refused employment for any medical finding has a handicap under section 503 of the Vocational Rehabilitation Act of 1973, and they demand you should hire the applicant regardless of what the normal course of disease progression will be. Despite the stand taken by the OFCCP, in my view, it is unreasonable and contrary to commonsense to place an individual in a position where his physical or mental health can be made worse or injury can result to other people.

Southern Pacific Transportation Co. strongly believes that only a competent physician who is well acquainted with railroad job responsibilities and the individual's medical capabilities should determine if an existing physical condition will prove detrimental to a person's well-being or to the safety of other employees in a particular job assignment.

Southern Pacific Transportation Co. screens individuals according to job requirements and has placed over 1,000 handicapped people in various job categories. We work closely with State and private rehabilitation groups and support an active in-house rehabilitation program. Southern Pacific Co. alters the workplace and job assignments for risk individuals, where possible. Because of the nature of the industry, however, it is impossible to modify many job responsibilities and still perform the job which is required to run the railroad. Many of the jobs are mechanized—for example, overhead cranes, cherrypickers, tie tampers—but there still remains a need for many individuals to perform arduous activities. Many employees are required to climb on and off moving trains, work on ladders, operate air hammers, and plain old-fashioned pick and shovel activities.

At a Western Occupational Medical Association meeting in Monterey, Calif., this last weekend, it was repeatedly charged that OSHA to date has cost the American people over \$25 billion, with no discernible change in the accident rate of American industry.

In my view, the primary goal of OSHA should be to achieve a cooperative effort with the health professionals in industry in protecting the health and safety of its employees. If OSHA is to assist in reducing industrial accidents and disease, they should direct more efforts to appropriate job placement.

I feel OSHA's current actions are comparable to requiring the utilization of shoulder pads and helmets for a football team, instead of emphasizing that the individuals who play the game should be physically fit and given assignments so that they could safely and effectively perform before they are allowed to don the pads and helmets.

At Southern Pacific Transportation Co. an attempt is made to become thoroughly acquainted with the individual's physical abilities and with potential job responsibilities. If it is felt that the individual can perform a job in a safe, efficient manner, he is cleared medically. If there are medical conditions which warrant specific medical restrictions, these are enforced. If it is impossible for the individual to perform the job with these restrictions, an attempt is made to place the individual into another occupation. Injured employees are often retrained and rehabilitated to qualify for other occupations.

Medical standards are used by Southern Pacific to make recommendations for appropriate job placement. The ultimate objective is to insure that employees are placed in occupations that they can efficiently and safely perform. Applicants may be refused employment for specific jobs if they:

First, have a contagious, infectious, or incapacitating condition which would endanger the health of others or would represent a hazard to oneself and/or others in the performance of duty.

Second, are medically incapable of completing the required training to achieve acceptable job performance.

Third, would require repeated excessive lost time due to illness.

Fourth, have a physical condition which would likely result in a physical disability within a relatively short period of time.

Fifth, demonstrate a lack of physical stamina, or insufficient body structure to be capable of physically performing the job in a safe and efficient manner.

Sixth, have a physical, emotional, or mental condition which might adversely affect the performing of his job responsibilities.

The underlying criteria for appropriate medical recommendations must be based on an understanding of the medical condition or conditions and their relationship with specific job responsibilities. Two or more medical conditions must be taken into account because of a combination of factors, on occasion, may make it impossible for the applicant to safely perform the job requirements, although each condition by itself would not be limiting. This determination must be made by the medical officer based upon his knowledge of the medical conditions and job requirements.

The decision to recommend against hiring in specific job categories on medical grounds should be based on a specific diagnosis following careful physical examination to verify the applicant has a particular disease or condition. The medical officer must then judge if the disease or condition will have specific undesirable consequences. The medical officer can then decide if the consequences of the disease or condition will interfere with the requirements of the job, or cause an undue safety situation.

Examples:

One, if the applicant has a skin condition which would be sensitive or irritated by chemicals, he may be restricted from working in or around a degreasing operation.

Two, if the applicant has asthma, he may be restricted from working in smoky or dusty environments.

Three, if the applicant has a congenital back deformity, he may be restricted from jobs requiring prolonged bending, twisting, or heavy lifting.

Four, if the applicant has diabetes and is on insulin, he may be restricted from working in and around moving equipment or working on unprotected elevations.

Because of the type of job assignments which exist in the railroad industry and because of the number of back injuries, Southern Pacific places special emphasis on a complete medical history and examination for possible back disease. This is augmented by the routine use of preemployment X-rays of the low back for persons applying for jobs which require arduous activities; that is, heavy lifting, frequent bending, stooping, and twisting.

In order to make a more uniform recommendation to industry, the Industrial Medical Association formed an ad hoc committee in April of 1962.¹ They published their results in the *Occupational Medicine Journal* in 1964 and summarized 33 spinal groups which they considered for job placement based on the activity of the occupation involved. This article has been used by many industries, including Southern Pacific, for many years as a standard for job placement.

In 1978, however, Southern Pacific reviewed and changed its X-ray standards. I have attached the current standards which we are using which is exhibit A. Over 30 percent of the conditions which had previously resulted in medical restrictions were eliminated and current X-ray findings which require restrictions from arduous activities are realistic and in our experience beneficial to employees, the railroad, and the public. These standards were reviewed by many orthopedists on the west coast and they uniformly agreed that applicants for employment with class V backs should be restricted from lifting in excess of 50 pounds and from performing jobs which require frequent twisting, bending, stooping, pushing, pulling, or getting on and off moving equipment.

The Southern Pacific Medical Department made a complete review of the literature with reference to low back X-ray screening. The following is a brief summary of the investigative study. I have an attachment labeled "E" which will give the specific references and I will only refer to a few of these.

However, Dr. W. F. Becker reported that of 561 people employed who were not examined with the preemployment X-rays there was an injury frequency of 43.7 percent. However, following preemployment X-ray screening this was reduced to 3.6 percent.

Dr. Kosiak further showed the worth of low back X-ray screening on a different population where back injuries were decreased despite a 30-percent increase in the work force and a 60-percent increase in the number of man-hours worked.

Dr. E. B. Coulter, in 1956, concluded in his study that preemployment back X-ray is an excellent method of decreasing back disabilities.

Dr. W. F. Becker in 1961 showed a marked decrease in the number of back injuries and severity following X-ray screening.

In 1973, the American College of Radiology held a combined meeting with NIOSH and other medical specialists, including or-

¹ This committee was charged with the responsibility of developing descriptive criteria for the use of low back X-rays in preplacement screening and to determine if a defect detected only by X-rays should be a contraindication for placing individuals on jobs which would increase the likelihood of low back injury.

thopedics and occupational medicine, and this has been referred to by Dr. Rogers; 15 of the 16 orthopedic surgeons present at that meeting concluded that preemployment back X-rays for arduous activities was a valid examination and recommended its continuance. They further recommended that individuals demonstrating low back X-ray findings similarly used by Southern Pacific should not be hired for jobs requiring arduous activities.

Dr. R. D. Moreton concluded after surveying 4,000 X-rays that 4 percent displayed spondylolisthesis, 6.8 percent has spondylolysis, of which the majority were bilateral. He further concluded that individuals with this condition should not be permitted to perform strenuous activity.

Dr. Moreton further concluded in a separate paper that time loss due to injury was greatly reduced by back X-ray screening.

Dr. S. F. Stewart stated that spondylolisthesis, sacralized transverse process and narrowing of intervertebral disk were changes most commonly contributing to low back pain.

Dr. C. F. Runge¹ concluded that individuals who had X-ray anomalies had more difficulty in recovering from accidents and the severity of their problems were greater.

Dr. R. L. Diveley stated that very few applicants gave a history of any previous spinal injury or low back disability despite many X-rays revealing compression fractures and evidence of dye in the neural canal. He stated that after the X-ray findings, further questioning often refreshed the applicants' memories of previous accidents and low back pain. In his study he reported low back X-ray screening reduced lost man-days in accidents from 8,230 to 1,806.

There had been no studies published specific to the railroad industry on our literature search so the following study was performed for Southern Pacific. This research compared the development of back disability between two groups of workers performing the same arduous activities—so-called maintenance-of-way employees—one group who had been screened with low back X-ray and one who had not been screened. The complete study is exhibit C attached to the back of the paper. The results of this paper revealed that applicants for laboring jobs with low back X-ray changes have six times the risk of developing disability from low back pain as the group that was screened. This is a very significant finding and an opportunity to practice preventive medicine with scientific validity.

I might state that at the time this paper was originally undertaken we were using a different X-ray standard than we are using today and that if we were to use today's standard, instead of being 6 times the risk for developing disability, it would probably be 10 times, which equates to 1,000 percent.²

¹ Dr. C. M. McGill in 1968 concluded that preemployment back X-rays significantly reduce the number of compensable back problems.

Dr. W. F. Torgerson concluded that routine back X-rays were useful in evaluating patients with low back pain.

Dr. Torgerson further reported a marked increase in spondylolisthesis, spondylolysis and degenerative disk disease in the group that had backache complaints.

Dr. W. J. Harley in 1972 concluded that you cannot completely eliminate back injuries; however, preplacement back X-rays are a useful adjunct for appropriate job placement.

Dr. W. A. Simril concluded that low back X-ray screening was of great value in decreasing on-the-job accidents.

² Exhibit B compares several authors' recommendations against arduous activities compared to Southern Pacific.

The important thing I feel in practicing preventive medicine is to prevent pain and suffering and I feel that preemployment screening is an excellent way to do this. I personally, however, have been involved in many lawsuits where the only finding was an abnormal back X-ray and complaint of pain. I notice following my testimony that Dr. Rockey and Dr. Omenn are going to be testifying and they published a paper recently that was called the "Discriminatory Aspects of Preemployment Screening for Low Back X-Ray Examination in the Railroad Industry," and I'd like to make one comment or two on this before I close.

On page 207 of this article they give references to back up their conclusions. I have brought these articles with me and I'd like to make a couple of comments on these.

In the article by Selikoff which was published in the Journal of American Medical Association, August 22, 1953, it states, "They were not screened except those persons with obvious pathological changes such as herniated intervertebral disks, tuberculosis, or other diseases." In this particular paper those medical conditions which caused the most problems were not even included in this particular paper. They also stated in this particular paper that such a condition can be of the utmost importance in industrial liability in instances in which injured employees may claim aggravation of a preexisting condition—this summarizes the necessity for low back X-rays on applicants for arduous work.

They quote from Dr. Torgerson. In his paper on page 851 he states,

Of the 217 asymptomatic patients, 22 percent had narrowing of the intervertebral disc; however, of the symptomatic patients, 56 percent of the patients had narrowing of the intervertebral disc or herniated intervertebral discs.

I won't go into detail on the other papers except to mention that the references are quite conclusive as far as I'm concerned in not only recommending but almost insisting on the performance of preemployment back X-rays.

In conclusion, I hope it is evident from my testimony that workers should not be permitted to assume the risks involved in their employment. Even though they may be advised of potential dangers, not only because of the employer's general concern for their individual safety but as importantly the concern for the safety of the public and fellow workers. As I have pointed out earlier in my testimony, regulations governing the safety of employees are necessary but often are in direct conflict with each other from different Government agencies. Industry must cooperate with Government but Government must cooperate and support industry's efforts in solving their problems.

In closing, I want to emphasize that Southern Pacific Transportation Co.'s foremost concern is the safety of its employees and the public.

[The prepared statement of Dr. Meyers follows:]

PREPARED STATEMENT OF DR. JOHN E. MEYERS

Mr. Chairman, members of the Committee, I am Dr. John Meyers. I am Chief Medical Officer for Southern Pacific Building, 1 Market Plaza, San Francisco, CA. I am a graduate of the College of Medicine, University of Utah, and a specialist in preventative and occupational medicine. I have been involved in preventative medicine for the last 21 years, and have had the opportunity to work with various

companies, including the United States Air Force, during that time. I am a graduate of the United States Air Force School of Aviation Medicine, and have worked for U.S. Steel Corporation for a period of 4 years; IBM for 5 years; and Southern Pacific Transportation Company since 1973. I am still an active member of the U.S. Air Force Reserve, where I continue to practice preventative medicine. I have had extensive experience in heavy industry and light industry before coming to work for the railroad. However, since coming with the railroad, I find it is necessary to practice medicine in a far different manner, primarily because of the Federal Employers Liability Act, which is a federal law governing railroad employers' obligations to its employees. Railroad workers, unlike those in virtually every other industry in the United States, are not governed by workman's compensation laws. They are governed by the Federal Employers Liability Act.

Under the Federal Employers Liability Act (45 USC) a railroad employee cannot be assigned to a job if the individual creates a safety hazard to himself, fellow employees or the public. Under FELA, an employee may file suit in either state or federal court against the employer for injury incurred on the job.

The courts have liberally interpreted the requirement of the common carrier to provide a safe place to work. The Supreme Court of the United States has said that whenever a railroad employee under FELA is injured, and if there is any evidentiary basis upon which reasonable minds could believe that reasonable care might have required additional safety measures which were not taken, and which, in fact, contributed in whole or in part to cause the injury and/or death, the case should be submitted to the jury. The language of this decision then supports the proposition that there is an obligation on the part of the common carrier to anticipate and institute additional safety measures to make the place of work a safe one. The courts have also said the plaintiff, as such, is not required to prove that the common carrier had actual or constructive notice as to the unsafe condition, and that this is a question for jury determination; and that presumption is that the employer has notice, since he controls the place of work and/or the assignments which the employee must carry out. For example, last year in Oakland, California, I released an employee with a history of emotional problems to return to work. Shortly after his return to work he shot a fellow-employee. The employee who was shot sued the railroad under FELA law for not providing a safe place to work. This is the second such case I have experienced in Oakland in the past two years.

Our attorneys advise me that the court could instruct a jury that the plaintiff employee's burden of proof is to show that the cause of injury is one which in natural continuing sequence produced an injury and without which the injury would not have occurred. In other words, the jury need find only that the railroad's supposed negligence played some part in causing the plaintiff injuries. For example, if an employee with a known back condition were allowed to work in a job which was known to be excessive to his physical abilities and he injures himself, a causal relationship can be asserted by the plaintiff against the railroad. Failure to furnish adequate help has been held to be negligence under FELA. If an employee with a known medical condition such as degenerative arthritis in his back was assisting a fellow-employee in lifting, and he dropped his share of the load and in turn caused injury to a fellow-employee, it could be claimed that adequate help was not provided by the railroad.

Thus, liability can be claimed following injury upon evidence that the railroad negligently permits an employee known to be psychotic or known to have potential physical disabilities to work on the property, with the result being that said employee inflicted harm or injury to a co-worker.

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Our attorneys advise me that FELA imposes an obligation on railroad employers to provide its employees a "reasonably safe place to work". The Act specifically provides, and various court interpretations have held, that contributory negligence and assumption of risk by the employee will not be a bar to recovery.

A court has found that "no employee shall be held to have assumed the risk of his employment in any case where the violation by any such common carrier of any

statutes enacted for the safety of employees contributed to the injury or death of such employee".

As an example, last year I was personally sued as an officer of the company for malpractice because an employee with a back condition that I had released to return to duties on advice of his attending physician, aggravated his back problem in the normal performance of his job.

FELA VERSUS THE OFFICE OF FEDERAL CONTRACT COMPLIANCE PRACTICE (OFCCP)

The health and safety of individuals who may be injured as a result of action forced by the OFCCP was not anticipated by the FELA. The two are inconsistent and contradictory. The OFCCP has taken the position that anyone who is refused employment for any medical finding has a handicap under Section 503 of the Vocational Rehabilitation Act of 1973, and they demand you should hire the applicant regardless of what the normal course of disease progression will be. Despite the stand taken by the OFCCP, in my view it is unreasonable and contrary to common-sense to place an individual in a position where his physical or mental health can be made worse or injury can result to other people.

Southern Pacific Transportation Company strongly believes that only a competent physician who is well acquainted with railroad job responsibilities and the individual's medical capabilities should determine if an existing physical condition will prove detrimental to a person's well-being or to the safety of other employees in a particular job assignment.

Southern Pacific Transportation Company screens individuals according to job requirements and has placed over 1,000 handicapped people in various job categories. We work closely with state and private rehabilitation groups and support an active in-house rehabilitation program. Southern Pacific Company alters the work place and job assignments for risk individuals, where possible. Because of the nature of the industry, however, it is impossible to modify many job responsibilities and still perform the job which is required to run the railroad. Many of the jobs are mechanized: (For example, overhead cranes, cherry pickers, tie tampers) but there still remains a need for many individuals to perform arduous activities. Many employees are required to climb on and off moving trains, work on ladders, operate air hammers and plain old-fashioned pick and shovel activities.

At a Western Occupational Medical Association meeting in Monterey, California this last weekend, it was repeatedly charged that OSHA to date has cost the American people over \$25 billion, with no discernible change in the accident rate of American industry.

In my view, the primary goal of OSHA should be to achieve a cooperative effort with the health professionals in industry in protecting the health and safety of its employees. If OSHA is to assist in reducing industrial accidents and disease, they should direct more efforts to appropriate job placement.

I feel OSHA's current actions are comparable to requiring the utilization of shoulder pads and helmets for a football team, instead of emphasizing that the individuals who play the game should be physically fit and given assignments so that they could safely and effectively perform before they are allowed to don the pads and helmets.

At Southern Pacific Transportation Company an attempt is made to become thoroughly acquainted with the individual's physical abilities and with potential job responsibilities. If it is felt that the individual can perform a job in a safe, efficient manner, he is cleared medically. If there are medical conditions which warrant specific medical restrictions, these are enforced. If it is impossible for the individual to perform the job with these restrictions, an attempt is made to place the individual into another occupation. Injured employees are often retrained and rehabilitated to qualify for other occupations.

Medical standards are used by Southern Pacific to make recommendations for appropriate job placement. The ultimate objective is to ensure that employees are placed in occupations that they can efficiently and safely perform. Applicants may be refused employment for specific jobs if they:

- (1) Have a contagious, infectious or incapacitating condition which would endanger the health of others or would represent a hazard to oneself and/or others in the performance of duty.
- (2) Are medically incapable of completing the required training to achieve acceptable job performance.
- (3) Would require repeated excessive lost time due to illness.
- (4) Have a physical condition which would likely result in a physical disability within a relatively short period of time.

(5) Demonstrate a lack of physical stamina, or insufficient body structure to be capable of physically performing the job in a safe and efficient manner.

(6) Have a physical, emotional or mental condition which might adversely affect the performing of his job responsibilities.

The underlying criteria for appropriate medical recommendations must be based on an understanding of the medical condition or conditions and their relationship with specific job responsibilities. Two or more medical conditions must be taken into account because of a combination of factors, on occasion, may make it impossible for the applicant to safely perform the job requirements, although each condition by itself would not be limiting. This determination must be made by the medical officer based upon his knowledge of the medical conditions and job requirements.

The decision to recommend against hiring in specific job categories on medical grounds should be based on a specific diagnosis following careful physical examination to verify the applicant has a particular disease or condition. The medical officer must then judge if the disease or condition will have specific undesirable consequences. The medical officer can then decide if the consequences of the disease or condition will interfere with the requirements of the job, or cause an undue safety situation.

Examples:

(1) If the applicant has a skin condition which would be sensitive or irritated by chemicals, he may be restricted from working in or around a degreasing operation.

(2) If the applicant has asthma, he may be restricted from working in smoky or dusty environments.

(3) If the applicant has a congenital back deformity, he may be restricted from jobs requiring prolonged bending, twisting or heavy lifting.

(4) If the applicant has diabetes and is on insulin, he may be restricted from working in and around moving equipment or working on unprotected elevations.

PREPLACEMENT BACK SCREENING

Because of the type of job assignments which exist in the railroad industry and because of the number of back injuries, Southern Pacific places special emphasis on a complete medical history and examination for possible back disease. This is augmented by the routine use of pre-employment X-rays of the low back for persons applying for jobs which require arduous activities; i.e. heavy lifting, frequent bending, stooping and twisting.

In order to make a more uniform recommendation to industry, the Industrial Medical Association formed an Ad Hoc Committee in April of 1962. This committee was charged with the responsibility of developing descriptive criteria for the use of low back X-rays in pre-placement screening and to determine if a defect detected only by X-ray should be a contraindication for placing individuals on jobs which would increase the likelihood of low back injury.

The Ad Hoc Committee's article was published in the Journal of Occupational Medicine in September, 1964 and summarized 33 spinal groups which they considered for job placement based on the activity of the occupation involved. This article has been used by many industries, including Southern Pacific, for many years as a standard for job placement.

In 1978, however, Southern Pacific reviewed and changed its X-ray standards. See attached Exhibit A. Over 30 percent of the conditions which had previously resulted in medical restrictions were eliminated and current X-ray findings which require restrictions from arduous activities are realistic and in our experience beneficial to employees, the railroad, and the public. These standards were reviewed by many orthopedists on the West Coast and they uniformly agreed that applicants for employment with Class V backs should be restricted from lifting in excess of 50 lbs. and from performing jobs which require frequent twisting, bending, stooping, pushing, pulling or getting on and off moving equipment.

MEDICAL RESEARCH OF BACK X-RAY SCREENING

The Southern Pacific Medical Department made a complete review of the literature with reference to low back X-ray screening. The following is a brief summary of this investigative study.

Dr. W. F. Becker reported a rejection rate of 24.5 percent following examination with X-rays of 1,062 men. He also noted that an investigation of industrial back injuries revealed a relatively great number of back injuries in employees starting on new jobs to which they are not accustomed. This tendency makes injury comparison difficult between new and old employees. Following are back injury comparisons of

men who had no specific examination placement and a group of employees who had met his standard requirement with back screening X-rays.

Employees	Number	Back injuries	
		Number	Percent
Not examined	561	245	43.7
Examined	139	5	3.6

He also observed that the frequency rate on lost time and light work cases declined markedly following X-ray screening of low backs.

Dr. W. F. Becker in October, 1952, concluded that back X-rays are of great importance and often a deciding factor in determining the employee's physical ability.

Dr. M. Kosiak states "That his criteria for job placement are generally in keeping with the IMA Ad Hoc Committee of 1964, with some minor variations. Absolute rejection is recommended only in persons with severe back injuries, spondylolysis, spondylolisthesis, destruction of bone and joint regions, and marked narrowing of intervertebral disc space." Dr. Kosiak is convinced after his experience with pre-employment X-ray screening that the number of back problems decreased and he stated, "In spite of the increased national trend in the frequency, severity and cost of industrial back injuries, our program reversed the trend in the 3M Corporation."

Dr. Kosiak further showed the worth of low back X-ray screening on a different population where back injuries were decreased despite a 30 percent increase in the work force and a 60 percent increase in the number of man hours worked.

Dr. E. B. Coulter, in 1956, concluded in his study that pre-employment back X-ray is an excellent method of decreasing back disabilities.

Dr. W. F. Becker in 1961 showed a marked decrease in the number of back injuries and severity following X-ray screening.

Dr. J. E. Burch concluded careful examination of the spine and extremities with low back X-rays will help eliminate candidates with definite or potential disabilities of the spine.

In 1973 the American College of Radiology held a combined meeting with NIOSH and other medical specialists, including orthopedics and occupational medicine. Fifteen of the sixteen orthopedic surgeons present at that meeting concluded that pre-employment back X-rays for arduous activities was a valid examination and recommended its continuance. They further recommended that individuals demonstrating low back X-ray findings similarly used by Southern Pacific should not be hired for jobs requiring arduous activities.

Dr. R. D. Moreton concluded after surveying 4,000 X-rays that 4 percent displayed spondylolisthesis, 6.8 percent has spondylolysis, of which the majority were bilateral. He further concluded that spondylolysis was necessary to produce spondylolisthesis and individuals with this condition should not be permitted to perform strenuous activity.

Dr. Moreton further concluded in a separate paper that time loss due to injury was greatly reduced by back X-ray screening.

Dr. S. F. Stewart stated that spondylolisthesis, sacralized transverse process and narrowing of intervertebral disc were changes most commonly contributing to low back pain.

Dr. C. M. McGill in 1968 concluded that pre-employment back X-rays significantly reduce the number of compensable back problems.

Dr. W. F. Torgerson concluded that routine back X-rays were useful in evaluating patients with low back pain.

Dr. Torgerson further reported a marked increase in spondylolisthesis, spondylolysis and degenerative disc disease in the group that had backache complaints.

Dr. C. F. Runge concluded that individuals who had X-ray anomalies had more difficulty in recovering from accidents and the severity of their problems were greater.

Dr. W. J. Harley in 1972 concluded that you cannot completely eliminate back injuries; however, preplacement back X-rays are a useful adjunct for appropriate job placement.

Dr. W. A. Simril concluded that low back X-ray screening was of great value in decreasing on-the-job accidents.

Dr. R. L. Diveley stated that very few applicants gave a history of any previous spinal injury or low back disability despite many X-rays revealing compression fractures and evidence of dye in the neural canal. He stated that after the X-ray findings, further questioning often refreshed the applicants' memories of previous accidents and low back pain. In his study he reported low back X-ray screening reduced lost man days in accidents from 8,230 to 1,806.

Dr. A. E. Colcher concluded that there was a high potential for low back instability with transitional lumbar segments, spondylolysis, spondylolisthesis, multiple Schmorl's nodes and degenerative discs.

Exhibit B compares several authors' recommendations against arduous activities compared to Southern Pacific.

There had been no studies published specific to the railroad industry in our literature search so the following study was performed for Southern Pacific:

SOUTHERN PACIFIC TRANSPORTATION COMPANY BACK X-RAY STUDY

This research compared the development of back disability between two groups of workers performing the same arduous activities—one who had been screened with low back X-ray and one who had not been screened. (See Exhibit C.)

The results revealed: Applicants for laboring jobs with low back X-ray changes as listed in "Class IV", Attachment A, have six times the risk of developing disability from low back pain as the group that was screened.

This is a very significant finding and an opportunity to practice preventive medicine with scientific validity.

CONCLUSION

I hope it is evident from my testimony that workers should not be permitted to assume the risks involved in their employment. Even though they may be advised of potential dangers, not only because of the employer's general concern for their individual safety but as importantly the concern for the safety of the public and fellow workers. As I have pointed out earlier in my testimony, regulations governing the safety of employees are necessary but often are in direct conflict with each other from different government agencies. Industry must cooperate with government but government must cooperate and support industry's efforts in solving their problems.

In closing, I want to emphasize that Southern Pacific Transportation Company's foremost concern is the safety of its employees and the public.

SOUTHERN PACIFIC COMPANY PRE-PLACEMENT X-RAY CLASSIFICATIONS Exhibit A

Classes I, II and III - no restrictions required
 Class IV - restrictions may be necessary
 Class V - restrictions are necessary

Class I

Normal, no pathology.

Class II

Anomalous transverse process; no anomalous joint
 Spina bifida occulta - sacral.
 Six lumbar vertebrae.
 Lumbar ribs.
 Sacralization transverse process, bilateral, complete.
 Scoliosis, mild, compensated, no associated pathology.

Class III

Osteo-arthritis, multiple spicule, two MM or less.
 Spondylosis - mild.
 Sacralization transverse process, unilateral complete
 Lumbarization of transverse process, no anomalous joint.
 Schmorl's nodule
 Increased lumbosacral angle 45° to 60° degrees.

Class IV

Fracture transverse process, single ununited.
 Persistent vertebral body epiphysis (Scheuerman's Disease).
 Osteoarthritis, multiple spicules, 3MM or over.
 Spondylosis - severe
 Fracture vertebral body, old, definite.
 Generalized or metabolic disease, any type.
 Anomaly of vertebral body, Butterfly vertebrae, Hemivertebrae, etc.
 Schmorl's nodule, multiple (3 or more), marked or severe

Class V

Fracture transverse process, multiple ununited
 Anomalous or ununited articular facet with little or no hypertrophic arthritis.
 Spina bifida occulta, any vertebrae cephalad to L-5.
 Increased lumbosacral angle - 60° or over.
 Osteoarthritis, hip or hips.
 Rheumatoid, intervertebral disc or destructive arthritis.
 Narrowed lumbosacral joint, definite, marked.
 Scoliosis, severe or moderate with hypertrophic arthritis.
 Spondylolysis (defect pars interarticularis).
 Spondylolisthesis, any degree.
 Evidence of previous back surgery or disc surgery.
 Osteoporosis.
 Metastatic bone tumor or any other definite bone tumor.
 Hemangioma.
 Sacralization or lumbarization with definite anomalous joint.

(X-ray examinations of the lumbar spine shall include five views of the L/S spine, AP, lateral, right and left obliques and a cone view of the L/S joint.)

Exhibit B

TABLE 1
SELECTED X-RAY ABNORMALITIES OF THE LUMBOSACRAL SPINE
(Ability to do heavy labor: + accepted, - rejected, *accepted most cases)

X-Ray Abnormality	Coulter (1956) 5	Becker (1961) 6	Kelly (1965) 7	Burch (1965) 8	Ad Hoc Committee Bond Tucson Revision (1964) 9	Tucson Revision (1973) 9	Present Study Current	Present Study Prior to 1974
Spondylolisthesis	-	-	-	-	-	-	-	-
Moderately Increased lumbosacral angle	*	+	+	+	+	+	+	+
Narrowing of lumbosacral disc space	+	*	-	-	-	*	-	-
Marked Narrowing	*	-	-	-	-	-	-	-
Lumbarization of S-1 complete		+	+	+	+	+	+	+
incomplete		-	-	-	-	-	-	-
Sacralization of L-5 complete	*	+	+	+	+	+	+	+
incomplete		-	-	-	-	-	-	-
Prior lumbar spinal fusion		-	-	-	-	-	-	-
Prior lumbar laminectomy		-	+	-	-	-	-	-
Moderately Advanced Osteoarthritis	*	-	+	-	-	-	-	-
Scoliosis - mild	+	+	+	-	-	-	+	+
severe	+	-	-		+	+	+	+
Schmorl's node	+	+	-	+	-	-	-	-
Spondylolysis		-	-	-	-	-	+	+

EFFECT OF PRE-EMPLOYMENT SCREENING BY LOW BACK X-RAY
ON INCIDENCE OF LOW BACK DISABILITY

A HISTORICAL PROSPECTIVE STUDY OF
THE SOUTHERN PACIFIC TRANSPORTATION CO. WORKFORCE

ABSTRACT

In order to estimate the effect of pre-employment screening by back x-ray on the incidence of low back disability, a study was undertaken in the spring of 1980. This study examined the rates of lower back disabilities among current, active, non-exempt employees of the Mechanical and Maintenance of Way (M&M) Departments at the Southern Pacific Transportation Company (SPTC). Rates were calculated for employees hired prior to the time the x-ray screening was instituted and compared to rates for those hired after that time (screened by x-ray). The relative risk of lower back disability in the unscreened, as compared to the screened group, was 1.5. This figure changed only slightly with age adjustment (1.7). Currently, approximately 10% of potential employees are screened out by x-ray. Assuming that this 10% constitutes a "high risk" group hired before screening was instituted, this group is estimated to have six times the rate of back injuries as the "normal" x-ray group.

INTRODUCTION:

In the Spring of 1980, a study was carried out by Southern Pacific Transportation Company which attempted to estimate the effect of pre-employment x-ray screening on rates of lower back disabilities. Since employees rejected because of x-ray findings are not hired, it is not possible to directly observe the rate of disability in this "high risk" group. Therefore, it was necessary to look at employees hired prior to the time the x-ray standard was instituted. Prior to 1961 potential employees in the Mechanical and Maintenance of Way Departments were not given a back x-ray. The same was true prior to 1949 in the Operating Department. However, computerized data was only available for current employees. Therefore, it was decided to only analyze data for the M&M since one-third of current employees were hired prior to the "screening date" while for Operating only 15% were hired prior to the corresponding date.

MATERIALS AND METHODS:

Selection of Disability Cases

Since 1969 all disability claims by SPTC employees have been computerized. The existence of this computer file made it possible to identify all cases of lower back disability among

- 2 -

current employees which occurred since that time. The Medical Department, under Dr. John E. Meyers, specified the relevant disability codes. The Computer Services Department, under Angelo Anaconatani's direction prepared a list of all current, active employees in California, with one of the selected disability codes. These codes and the numbers selected are contained in Table I.

As mentioned above, it was decided to limit analysis to employees in M&M. There were 130 persons; if an individual had more than one disability, only the first was selected. Of these, 60 were hired prior to 1961 and had no record of x-ray. In addition, two individuals hired after that time had a clear notation of "no x-ray" found in the medical record. They were included in this group. These 62 individuals constituted the "unscreened group". A definite record of x-ray was found for 50 individuals hired after 1961. In addition, one individual hired in 1976 for whom no record was found was included in this group. In addition, 17 persons hired after 1961, for whom medical records and pre-employment exams were available but for whom no mention of x-ray could be located were deleted from further analysis.

Selection of population at risk:

These cases must be examined relative to the population at risk. In April 1980 there were 7,041 active employees in M&M of whom 2,312 were hired prior to 1961 and 4,729 after that time.

Calculation of person-years of observation:

Employees hired at different times obviously have unequal time periods during which they are at risk of a disability which will be recorded by SPTC. The "observation period" is that time period during which an individual was actively employed and during which disabilities were computerized. The standard technique for handling unequal observation periods is to calculate "person-years of observation". Each year that an individual is under observation (that is, employed during the time disabilities are computerized) contributes one "person-year" of observation.

Calculation of age-adjusted rates:

In order to examine the effect of age on incidence of lower back disability, it was necessary to calculate age-specific incidence rates. For this purpose the work force was divided into three age groups; under 35, 35-49 and 50 and over. The number of person-years of observation contributed by each current employee to each of these age groups was calculated. These individual contributions were then added to provide the total number of person-years of observation in each age group. This was done separately for those hired before and after 1961. This calculation was performed by computer. The program was written by Mary Anne Armstrong under my direction. In all there were 59,346 person-years of observation of which 26,588 were in the pre-61 group.

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Calculation of rates and estimates of risk:

A simple comparison of number of cases to population at risk provides a crude rate. These rates are unsatisfactory because they do not take into account the differences in observation periods between the two groups. However, incidence rates can be obtained by dividing the number of cases in each group by the number of person years of observation for the group. If this is done for each age group the rates obtained are age-specific incidence rates. Finally, an overall comparison, which is adjusted for differences in the age-distributions of the two groups, is made by comparing the age-adjusted incidence rates. The ratio of these rates is called the relative risk. It compares the rate of back injury in the unscreened to that in the screened. The significance of this measure of risk can be tested.

RESULTSComparison of crude rates:

During the eleven years during which disabilities were computerized, there were 62 cases in the "unscreened group" out of a total population of 2,312 employees, while there were 51 cases in the screened group out of a population of 4,729. Therefore, the rates in the unscreened and screened groups were 2.68% and 1.08% respectively. In other words, among the total work force about 1.5% of the population can expect to have one or more lower back disabilities in a comparable time period. The comparison of these crude rates in the screened and unscreened suggests that the rate of injury in the unscreened group is about 2.5 times as great as in the screened. However, this figure is misleading because of the differences in observation periods for the two groups.

Adjusting for person-years of observation:

In the unscreened group, there were 25,588 person-years of experience accumulated; each individual was observed for about 11.5 years. However, in the screened group, the average observation time was only 6.9 years; the accumulated total was 32,758 person-years of observation. Therefore, the rates for the two groups were 2.33 injuries per 1000 person years and 1.56 injuries per 1000 person-years respectively. The ratio of these two rates gives the estimate of relative risk of 1.5. In other words, the unscreened group has 50% more lower back disabilities than the screened group.

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Calculation of age-adjusted rates:

Overall the incidence rates increased from 1.3 cases per 1000 person-years for those under 35 years to 2.6 cases per 1000 person-years for those 50 years and older. For this reason, age-specific incidence rates were computed and age-adjusted rates obtained. These are contained in Table III. The relative risk based on the age-adjusted rates was 1.7 which is in close agreement to the result for the unadjusted rates. This is due to the fact that numbers for the youngest age group were small in the unscreened group, while the rate for this group was highest. Conversely, the highest rate for the unscreened group was the oldest age group where the numbers were smallest. The age-adjustment gave each of these small, high risk, groups more weight.

Statistical Significance:

The incidence rates for lower back disability in the two groups are 2.33/1000 and 1.56/1000 respectively. While these rates are very small they are based on very large numbers. Therefore, the distribution of disabilities can be assumed to be binomial and the normal approximation can be applied to test the significance of the difference between these two rates. The Z value obtained is 2.14 which has a (one-tailed) significance probability of .0162.

Alternatively, it is possible to test the statistical significance of the odds ratio of 1.5. If the two rates were actually equal, this quantity would equal 1.0. Using the fact that the logarithm of the odds ratio has an approximately normal distribution, the appropriate z statistic has a value of 2.11, almost identical to the result obtained using the binomial comparison above.

By either method the difference in rates is highly statistically significant and with probability exceeding 98% could not have occurred by chance.

Estimating the rate of disability in the "high risk" group:

The screened population consists only of persons who passed the pre-employment screening by back x-ray. The unscreened group consists of two groups, those who would have been screened out by this test and those who would have passed. Call these two sub-groups the "high risk" and the "normal" groups. Approximately 10% of the MGM work force fails to pass the back x-ray screening test. Therefore, it is assumed that the unscreened group consists of 10% of the "high risk" population and 90% of the "normal" population. It is the presence of the "high risk" group that explains the elevated relative risk in the unscreened group. If the "normals" in the unscreened group are assumed to have an incidence rate equal to the rate in the screened population (1.56/1000) then the "high risk" group must have a rate of 9.3/1000 to make the overall rate for the unscreened group equal 2.33/1000. In other words, the relative risk of occurring lower back disability in the "high risk" group as compared to the "normal group" is

estimated to be 5.94.

DISCUSSION:

This study and the estimates derived from it probably underestimates the true relative risk of back disability in the unscreened population for two reasons. Only current employees were available for analysis. Therefore, any person with an injury severe enough to lead to retirement for disability would not be included. Secondly, any disability (with the minor exception of four cases) which occurred prior to 1969 would not be included in this analysis.

The results give strong direct evidence of the effectiveness of the back screening procedure in reducing the incidence of low back disability in an active employee population.

Exhibit C

APPENDIX I

METHOD OF CALCULATING RATE IN "HIGH RISK" GROUP

1. Let X denote the rate in the "high risk" group
2. Assume the high risk group is 10% of the unscreened group.
3. Assume the remaining 90%, the "normal" population, has the same rate as the unscreened group; 1.56/1000.

Then: The rate in the unscreened, 2.33/1000 is a weighted average of the rate in the "normal" group and that in the "high risk" group:

$$2.33 = (.90) (1.56) + (.10)X$$

$$9.26 = X$$

TABLE I

LOWER BACK DISABILITIES BY DISABILITY CODE

DISABILITY CODE	DESCRIPTION	NUMBER
56	Degenerative disc disease (lumbosacral)	4
73	Laminectomy	1
46	Herniated disc (degeneration)	4
47	Lumbar sprain - disc - laminectomy	10
19	Spine, laminectomy of	5
18	Spine, fusion of (injury)	11
27	Back injury-neck injury (NEC)	<u>229</u>
	TOTAL	264

TABLE II
DISTRIBUTION OF ALL EMPLOYEES LISTED WITH
LOWER BACK DISABILITY

<u>OCCUPATION</u>	<u>MEDICAL CHART FOUND</u>	<u>CHART NOT FOUND</u>	<u>TOTAL</u>
OPERATING	71	2	73
CLERICAL	54	3	57
MECH. & MAINT.WAY	116	14*	130
UNKNOWN	4	0	4
TOTAL	245	19*	264

*Includes 13 persons hired pre-1961 who were included in "unscreened" and one person hired after 1961 included in "screened".

TABLE III

AGE-SPECIFIC INCIDENCE RATES OF LOWER BACK
DISABILITIES AMONG UNSCREENED AND SCREENED
EMPLOYEES OF MCMW DEPARTMENTS

<u>AGE</u>	<u>UNSCREENED</u>			<u>SCREENED</u>		
	<u>NUMBER OF CASES</u>	<u>PERSON-YEARS</u>	<u>* RATE</u>	<u>NUMBER OF CASES</u>	<u>PERSON-YEARS</u>	<u>* RATE</u>
Under 35	3	656	4.57	25	20,471	1.22
35 - 49	26	13,359	1.95	20	9,654	2.07
50 and over	33	12,573	2.62	6	2,633	2.28
TOTAL	62	26,588	2.33	51	32,758	1.56

* CASES PER 1000 PERSON-YEARS

Mr. GORE. Thank you very much.

As I said at the outset, these are tough questions and I recognize the complicating factors in the railroad industry, the statutes that you referred to, Dr. Rogers, and the other matters involved; and I hope you understand that our principal interest is in examining the way your industry has resolved these issues in hopes that we might gain some insight into how society as a whole can better cope with quite similar issues which will soon be upon us with the advent of genetic screening.

Dr. Meyers, do you give X-rays to applicants for clerical positions?

Dr. MEYERS. No, only those that are going to be performing arduous type of activities or those type of activities which would place undue strain on the back.

Mr. GORE. So you do not, as a matter of routine, give X-rays to all job applicants?

Dr. MEYERS. No, sir.

Mr. GORE. What percentage of job applicants would you estimate receive back X-rays?

Dr. MEYERS. This would probably depend upon the year we're talking about. Right now there's no hiring going on to speak of. The turnover rate probably is much higher for clerical type workers than it is for what you might call the operational people, and so I'd say that the majority of the people do not receive X-rays who apply for jobs with Southern Pacific.

Mr. GORE. Was there ever a time when you did give X-rays to clerical workers?

Dr. MEYERS. When I first came to Southern Pacific they were performed on clerical type workers. I felt, however, that the incidence of stress and strain in those various kinds of jobs—and also because we were literally placing people in clerical type work who had had back injuries and we wanted to find a job for them—so we feel that it's not necessary to perform X-rays on those individuals.

Mr. GORE. When was that policy changed?

Dr. MEYERS. Roughly in 1974.

Mr. GORE. Dr. Rogers, do you restrict X-rays to those seeking employment in jobs that will place particular stress on their backs?

Dr. ROGERS. That is correct. We do not X-ray clerical employees.

Mr. GORE. Do you, Dr. Meyers, ask applicants if they have previously been denied employment for medical reasons?

Dr. MEYERS. I personally do no examinations on the applicants. These are done in local areas by physicians.

Mr. GORE. Does your company ask applicants if they have previously been denied employment on the basis of a preemployment back X-ray?

Dr. MEYERS. No, sir.

Mr. GORE. You do not ask. And does the company ask applicants if they had previously been denied employment for any medical reasons?

Dr. MEYERS. Medically, I can't answer that question. Whether personnel asks that question, I wouldn't be able to answer. We do on our medical form, though, ask if individuals have had specific medical conditions, whether they have been discharged from the

military for medical reasons; but that would be about the sum and substance of it.

Mr. GORE. Is it your response that you don't know if the company asks the other question?

Dr. MEYERS. No, sir.

Mr. GORE. Could you supply that for the record?¹

Dr. MEYERS. Yes, sir.

Mr. GORE. Dr. Rogers, does your company ask applicants if they previously have been denied employment on the basis of a back X-ray?

Dr. ROGERS. Yes, we do. On the medical history we ask if they have been denied employment for any reason. If the answer is yes, we ask for that reason. However, this does not preclude their employment.

Mr. GORE. Do you commonly contact the other company involved for details on the problem involved?

Dr. ROGERS. No, that is not our custom. We take the patient's history and do our own physical examination and arrive at our own conclusion. But the question is part of the history asked.

Mr. GORE. Who reads the X-rays that are made, Dr. Meyers?

Dr. MEYERS. All X-rays which are taken are reviewed by board certified radiologists. However, during the past 2½ years, every radiology report that reveals a bad back X-ray I personally have sent to my office for further review so it can be seen by at least two physicians. I have found that sometimes a radiologist may overread an X-ray and so that's one of the reasons why it's brought in and if I have any questions about it I'll take it to another radiologist to read. I'd say roughly 5 percent of the X-rays which I review I change the classification.

Mr. GORE. Do you have a board certified radiologist on your staff?

Dr. MEYERS. No.

Mr. GORE. You contract with a radiologist?

Dr. MEYERS. Yes.

Mr. GORE. Dr. Rogers, who reads your X-rays?

Dr. ROGERS. All of our X-rays are read by radiologists. I do not qualify as a radiologist. Then I accept their reports. If there is any question I then ask that the X-rays be submitted to us and these are sent to another radiologist for a comparable opinion.

Mr. GORE. When did your program of making X-rays begin? Are you aware of when that began?

Dr. ROGERS. Yes. This started in the late 1960's.

Mr. GORE. Dr. Myers?

Dr. MEYERS. It would depend with different crafts. In the paper that we have submitted on maintenance-of-way employees, the X-rays began in 1961.

Mr. GORE. All right. Now when you find a condition that you identify as predictive, are all applicants with that condition excluded from the jobs in question?

Dr. ROGERS. We balance the findings against the job requirements. For example, one congenital abnormality may be acceptable

¹ In answer to Congressman Gore's question, each applicant is asked if he has previously been medically rejected for employment. The reason for this question is to ascertain what the individual's medical capabilities are.

for a person who is going to be a clerk operator, but that same abnormality would not be acceptable for a trainman. We list our X-ray disqualifying conditions as potential disqualifying conditions, but in every case we attempt to balance the X-ray finding against the job requirement in the job specification.

Mr. GORE. Is the statement true for each job category? In other words, when you get a specific job category and you find a condition present from the X-ray, are all applicants with that condition denied a job in that specific job category?

Dr. ROGERS. No, not always, because we have another factor which is important to us, and that is the factor of age. The finding of spurs, for instance, in the back of a 45-year-old man is not significant, whereas it is in a 19-year-old. So for the same job category, we again are trying to balance all factors.

Mr. GORE. Dr. Meyers, the same question?

Dr. MEYERS. Basically, the same answer. First of all, anybody who I feel after reviewing not only the back X-ray but the total physical examination, if I feel he cannot perform a particular job, this is then discussed in an open panel with members of the employment department, with industrial relations, to see if it's possible to offer this individual another job, and each individual that we feel cannot perform a job he's applied for is sent a letter instructing him to contact the company if he's interested in applying for another type of occupation.

Mr. GORE. What have you two found to be the general incidence of these types of abnormalities that are under discussion in the general population? What percentage of the people can be expected to have such conditions?

Dr. MEYERS. Once again, like Dr. Rogers mentioned, you have to bring age into this. I mean, probably 50 percent of the people over the age of 50 have got some narrowing of their disk spaces and probably have got some degenerative arthritis. As far as the disease of spondylolisthesis and spondylolysis, the studies range anywhere from 3 to 6 percent. As far as transitional vertebrae indicating a current arthritic condition, this can be even 1 percent. In all of the X-rays that I review I found that since changing my X-ray standards that there is less than 10 percent of the people who will be affected or who will require specific job restrictions.

Mr. GORE. Dr. Rogers?

Dr. ROGERS. Essentially the same thing, varying with age and the job, but the disqualifying figure based on back X-rays alone may run 10 to 20 percent.

Mr. GORE. Is there a possibility that an applicant for the job of, say, switchman, might be turned down on the basis of a back X-ray by the Southern Railroad but accepted for employment by Southern Pacific? If the percentages are different, could there be different criteria involved?

Dr. ROGERS. I would say that our criteria are essentially the same. Of course, there is an individual variation in every railroad company, but overall, we follow guidelines that are fairly well set by the group of railway physicians joined together in the medical section of the Association of American Railroads.

Mr. GORE. Do you have a response to that, Dr. Meyers?

Dr. MEYERS. The same as Dr. Rogers.

Mr. GORE. Are the categories of abnormalities that we're talking about here identifiable only through X-rays?

Dr. MEYERS. Yes.

Dr. ROGERS. Most of them are identifiable only through X-rays.

Mr. GORE. Of those that can be identified only by X-rays, of those conditions that can be identified only by X-rays, do you both agree on which conditions should be grounds for excluding applicants?

Dr. ROGERS. I think we do because the greatest number of these are the conditions of spondylolysis and this is fairly standard throughout the railroad industry and I expect that Dr. Meyers will agree with me on that.

Mr. GORE. Are these preemployment X-rays commonly used in compensation suits later brought under the FELA?

Dr. MEYERS. Very frequently.

Dr. ROGERS. Yes.

Mr. GORE. Would you say that the anticipation of such suits plays a major role in the use of these X-rays?

Dr. MEYERS. It doesn't play a major role in my business. My primary reason for performing the preemployment X-ray is to let the individual know what his condition is so he can prevent a disability from occurring and I can't think of another area of preventative medicine where I can do as much good as I can in this particular classification.

Mr. GORE. Dr. Rogers?

Dr. ROGERS. Mr. Chairman, if it's permissible, I would like to defer to counsel on this because he is a strong backer of my preemployment X-ray program and I think the committee would like to have the benefit of his opinion.

Mr. GORE. That would be fine.

Mr. MITCHELL. To make sure I respond precisely to the question, would you repeat the question, please?

Mr. GORE. Does the anticipation of the use of these X-rays in compensation suits brought under FELA play a significant role in the company's decision to use them as frequently as they are used?

Mr. MITCHELL. The use of preemployment back X-rays is obviously intended to prevent the kind of injury which forms the basis for an FELA lawsuit. Your question, if I interpret it correctly, is whether or not we use preemployment back X-rays in order to create potentially defensive evidence; that is, evidence of the type that we could use against the employee when he brought a suit. And my response to that would be, no, we do not. That is not the purpose of the X-ray. It may be incidentally used in that way, but it is not the purpose for which it is given. The sole purpose for which the preemployment X-ray is given is to prevent potential injury to the employee by giving him a job assignment that he is not physically capable of discharging.

Mr. GORE. I realize that at some point the company may feel that it's damned if it does and damned if it doesn't, and I understand the nature of that dilemma. I'm concerned that similar dilemmas may impel wider use than necessary of a lot of other screening techniques for essentially the same sort of reasons. I mean, it may be that HAL antigen screening would provide the same evidence that you're getting with X-rays here, more cheaply and safer, and that might compel their use. I'm not suggesting that by any means.

I'm apprehensive about that possibility, but perhaps the Congress needs to examine the way the law promotes this.

Mr. MITCHELL. Mr. Chairman, if I may make one comment as a result of about 25 years of handling FELA suits, Dr. Meyers mentioned the damned if you do and damned if you don't syndrome. If you fail to give a preemployment back X-ray and as a result of that unnecessarily expose the particular employee to a hazard that he would have avoided had you given him the X-ray, you're wide open to an unlimited liability under the Federal Employers Liability Act in the event the employee is in fact injured. Moreover, if that same employee, as a result of his inability to perform his job safely, is responsible for the injury of another employee, you're faced with precisely the same situation.

So the failure of the railroad industry to give the preemployment back X-ray or the failure to act appropriately on the finding can expose the industry and the railroad to enormous Federal Employers Liability Act liability.

Dr. MEYERS. May I add one more comment to that?

Mr. GORE. Yes.

Dr. MEYERS. I think that your questions are so far pretty well focused toward the involved employee. I think even more important is the exposure of the public. When I pick up the paper and see whole towns evacuated because of a railroad accident and you see the potential for thousands of people to become injured and killed, this is one of the primary reasons why we have to insure that the individuals who operate our trains can do it in a safe and efficient manner.

Mr. GORE. Which railroads, to your knowledge, have terminated their X-ray screening programs?

Dr. MEYERS. I know that the Burlington did on a routine basis, even though they still perform back X-rays. The Union Pacific terminated their program. I've talked with their medical directors and asked them the reasons why, and the reasons why is because of feared lawsuits from the OFCCP. They didn't want to become involved in these programs. They didn't want to spend time trying to fight and so they dropped the X-ray program.

I think it was a poor decision and I think that when we can show that the back X-ray program can be defended and should be defended they will probably reinstitute their back X-ray program.

Mr. GORE. Dr. Rogers, do you know of any others that have terminated their X-ray program?

Dr. ROGERS. No. Those are the two roads that have terminated their back X-ray program.

Dr. MEYERS. I may add that the Santa Fe also discontinued their back X-ray program, but in talking to their medical director you get the same answer.

Mr. GORE. Now a number of studies have been conducted indicating that X-rays simply cannot be used to distinguish between symptomatic and asymptomatic workers. There's been an evolution in the data collected. Early on there was evidence that X-rays were predictive and then there was a period of dispute and as best as I can gather there seems to be a developing consensus which you two do not share that these X-rays are not predictive.

As medical directors for companies involved in such programs, how do you react to this kind of developing evidence? How do you evaluate the controversy as it now stands?

Dr. MEYERS. Well, I think you may have been absent when I was testifying to that particular problem. I mentioned that the paper that was printed by Dr. Rockey—

Mr. GORE. No, I was here when you discussed that at the end of your testimony where you cited—I got from your testimony that you took their source material and challenged its relevancy to support their conclusions.

Dr. MEYERS. There has been no article published to show that X-rays are not a good screening tool. There have been no studies prior to the Southern Pacific Railroad study that was specific to the railroad industry, and I think probably one thing that should be pointed out very clearly is that it's not the particular back condition that's the important thing. It's what you do to it. It's the type of stresses and strains you place upon it.

Mr. GORE. Dr. Rogers, how do you react to this developing controversy?

Dr. ROGERS. My reaction is that I admit, as I stated in my paper, that the X-ray is not 100-percent predictive, but when we find an abnormality in a young individual that we know predisposes to future injury, I think it's unfair to that individual to place him in a job that will put stress and strain on his back and aggravate that congenital difficulty. I think that much of the opinion that is back of some of these articles stems from the fact that these people are not aware of the railroad industry. They haven't been out there on the front line as we have been as medical directors of railroads and they really don't know the problem.

Mr. GORE. The stresses to which they are about to be subjected?

Dr. ROGERS. Exactly.

Mr. GORE. What percentage predisposition would justify such a decision? Let me give you a hypothetical case. We have been dealing in general terms because the argument is whether or not X-rays are: (a) predictive or, (b) not predictive. Let's suppose that an X-ray that uncovers a certain condition constitutes evidence that the individual involved will have a 5-percent greater chance than the average individual of incurring a job-related injury. Would you think that justified denying the person employment?

Dr. ROGERS. At 5 percent, no.

Mr. GORE. What about 10 percent?

Dr. ROGERS. Then you're getting on up there. But it has been shown by some studies—and I'm far from being a biostatistician—but it has been shown in some studies that the X-rays are predictive in 60 percent of the cases and I think this is worthwhile. I wanted to compliment Dr. Dixon on his presentation this morning that in the industrial community or in occupational medicine it's important that these people be trained in occupational medicine and know the factors in the job and that the care of the employee requires a good history, a good physical, and, when necessary, other ancillary studies such as back X-rays or in other industries spirometry and so on.

Mr. GORE. Well, the reason I asked the question is not to put you on the spot in any way, but I think that it's almost certain that 10

years from now, or 15 years from now or 20 years from now, we will see libraries of genetic information combined with epidemiological studies which converge into a catalog of probability figures which will tell employers what the percentage of occupational disease is likely to be at variance from the norm for a specific individual applying for a job.

Now if 5 percent is not fair but 10 percent is getting into the fair range, if that approach is transplanted into genetic screening, then you're going to have real chaos in hiring procedures it seems to me.

Let me ask you, Mr. Mitchell, under your reading of the FELA, if your company—and this is a hypothetical question—if your company had an X-ray which established that there was a 5-percent greater chance that the individual in question would incur an occupational injury and you decided that the person ought to be hired and the person later files suit after getting an occupational injury, would the preexistence of that 5 percent predictive X-ray be sufficient to send the case to the jury?

Mr. MITCHELL. In my opinion, there's no question but that it would, but on the premise that we were aware of the potential danger and we knowingly permitted the man to go to work. We would argue very strongly the point of view that I think you put in your question is true, and that is that this is not something for which we are responsible. The ultimate decision, however, would be made by the jury, as is the case in almost every FELA case.

Mr. GORE. But your company has an incentive to keep the decision away from the jury and with the court—with the judge—to keep the decision away from the jury rather.

Mr. MITCHELL. Not necessarily.

Mr. GORE. Well, let me ask the question in a different way. Would you advise legally the denial of employment in that job category to someone who had a 5-percent predictive X-ray or other indicator?

Mr. MITCHELL. If you're going to confine the arena of my advice solely to the Federal Employers Liability Act and eliminate all the other discrimination in employment acts to which we are subjected, my advice would be yes.

Mr. GORE. What about a 1 percent?

Mr. MITCHELL. I think you get to a point where those of us who have studied law would say it's *de minimis*.

Mr. GORE. Two percent?

Mr. MITCHELL. I don't know how, as a lawyer—

Mr. GORE. Somewhere between 2 and 5?

Mr. MITCHELL. If you came to a point where there is what I would consider to be any appreciable risk of injury, my advice would be if you have an opportunity to avoid it, avoid it. I do not believe that either medical science or what I perceive to be the future of genetics is sufficiently precise to draw the line between 1 and 2 percent. I'm not certain that there's anything that medically certain. But when you get up into the 5- and 10-percent range, as I think Dr. Rogers mentioned, you're beyond the realm of probable error and into the realm of where I think an injury an ordinary citizen is likely to say this company deliberately took a risk and we're going to make them pay for it.

Mr. GORE. Yes. Well, my point is, quite apart from a purely ethical determination of whether it's right or wrong to exclude someone from employment if there's an enhanced risk, there are preexisting ethical judgments embodied in statutes which will make it very difficult for companies to reach any apriori decisions.

Mr. MITCHELL. You're absolutely correct.

Mr. GORE. What other statutes might be in this category along with FELA?

Mr. MITCHELL. You mean in terms of the imposition of liability on employers?

Mr. GORE. Yes.

Mr. MITCHELL. Well, there are many other different kinds of compensation acts, but most of the industry—almost all of organized industry today is covered by one form or another of a workman's compensation act. Federal employees are covered by the Federal Employees Compensation Act. The longshoremen by the Harborworkers' Act and almost all State employees are covered by individual acts. The Jones Act and the FELA are parallel acts that as far as I'm aware are the only two remaining industrial compensation acts that predicate the ability to recover and the extent of the recovery on negligence and that's the heart of this problem.

Mr. GORE. Let me read to you, Dr. Rogers, a quote that was attributed to you at the 1973 "Conference on Low Back X-Rays" and ask you if this is an accurate quote and then explore with you some of the ramifications of it.

First of all, the quote:

It behooves the railroad industry to ensure through its medical departments that its employees are in top-notch physical condition and also that the medical departments provide the railroad industry with applicants who are as near perfect physical specimens as is possible for us to find. In the face of staggering claims and settlements, we feel we must do everything possible to exclude the potentially serious back injury.

First of all, is that accurate?

Dr. ROGERS. That is a correct quote, yes.

Mr. GORE. And do you stand by that statement today?

Dr. ROGERS. Yes, I do. I think it is inherent upon us as medical directors to furnish to the railroad people who are physically and mentally qualified to do their job.

Mr. GORE. The implications which are troubling to me, and not just within the context of your industry, are that if every industry involving strenuous physical labor insists upon perfect or near perfect physical specimens and science gives us increasingly accurate means of determining and defining perfect and near perfect, then we create some very difficult problems for possibly the majority of our citizens who will not fall in that category.

Dr. ROGERS. Here again, I think that this will depend on the expertise of the medical profession in arriving at a medical opinion of that back versus that job. We don't expect perfect backs. We'll never get them. But we do feel we should balance our findings on X-ray with what that back must be required to do.

Dr. MEYERS. May I add one comment there?

Mr. GORE. Sure.

Dr. MEYERS. You will find that industries look for people to perform particular jobs with specific capabilities. For an example,

when I was working with the United States Steel Corp., we put out a search for deaf individuals. In this particular job we only wanted deaf individuals to work in that occupation. This was an occupation inside of a 45-inch pipe where the decibel levels were extremely high and despite ear protectors it was impossible to protect their hearing. So we found a number of completely deaf individuals and trained them to do welding operations inside of a 45-inch pipe.

So it's not that every industry in every job category is looking for a perfect specimen. I think I summarized in my paper and I think Dr. Rogers would agree that we have to insure, however, that the individuals who are going to be able to perform the job can do it safely and do it effectively.

Mr. GORE. I assume that both of you provide gonadal shielding for male applicants?

Dr. ROGERS. This is recommended by all of our radiologists.

Mr. GORE. Do you in fact provide it?

Dr. MEYERS. We don't provide it, but it's routine for the department of radiology on all X-rays.

Mr. GORE. What about female applicants? I know it's difficult to provide similar shielding. Do you provide any such protection?

Dr. ROGERS. In the female applicant, we cannot get a satisfactory X-ray if we use gonadal shielding. Therefore, we have the requirement that the X-rays shall only be done at a certain time during the menstrual period.

Mr. GORE. When is that?

Dr. ROGERS. We like for this to be done within 10 days after the cessation of the menses.

Mr. GORE. What precautions do you take to protect people who are denied employment on the basis of back X-rays to prevent the adverse effect of labeling which make it difficult for them to find employment elsewhere?

Dr. ROGERS. In this regard, we advise the applicant that if he is further interested in the reason for his medical disqualification to have his personal physician write to me. In turn, I furnish this man's personal physician with all of the findings of our medical examination and give the reasons therefor.

Now if inadvertently we find something—say a tumor or a disease process in the spine such as tuberculosis of the spine or a tumor of the spine which the employee is not aware of, then we go directly to the employee and advise him that he should be seen by his personal physician immediately.

Mr. GORE. OK. Thank you very much. I appreciate very sincerely both of you—all of you coming to help us in this endeavor. I truly believe that the problems that we are going to face with regard to genetic screening are going to be very, very troublesome and we appreciate your assistance in helping us to understand the framework within which the proper questions have to be asked and I thank you very much.

Mr. MITCHELL. Mr. Chairman, could I make one final comment on the point you were making a moment ago? We, as a company policy, do not release medical findings without the consent of the person who's being examined, but I think it would be wise, if the committee is interested in exploring that particular concern, to consider it in the context of what the privacy acts of both the State

and Federal Governments impose on companies in terms of their ability to disseminate the kind of information that seems to be concerning you. It is very unlikely that any company with competent legal advice would make any wholesale distribution or any indiscriminate distribution of this kind of information.

Mr. GORE. If laws on the books already provide adequate protection in that area, that's some comfort and we can direct our attention more vigorously elsewhere. Thank you very much for appearing.

Our final panel today—well, actually we'll take these witnesses one by one. Our next to last witness is Dr. Paul Rockey, Medical Director of the U.S. Public Health Service in Seattle, Wash. Dr. Rockey, we are pleased to have you with us today and I understand you have a slide presentation which we are looking forward to. Without objection, the entire text of your statement will be put in the record at this point and we invite you to proceed with all of it or a summary, as you see fit.

**STATEMENT OF PAUL ROCKEY, U.S. PUBLIC HEALTH SERVICE,
SEATTLE, WASH.**

Dr. ROCKEY. Thank you, Mr. Chairman. I'm Dr. Paul Rockey. I'm Associate Director for Clinical Affairs at the U.S. Public Health Service Hospital in Seattle, Wash., and I'm assistant professor of medicine and health services at the University of Washington.

As we have heard this morning, preemployment screening of job applicants for health factors that might place them at increased risk for occupational disease or injury is a widespread practice. Findings from a health history, from a physical examination, and from specialized diagnostic tests often are used to assign employees to less hazardous duties, or to bar them from employment altogether.

A major factor that clearly must be taken into account is the validity or accuracy of the test used in screening. How well does that particular screening test select out those individuals who have a high probability of having or developing the disease or condition?

The predictive value of a screening test for a particular condition depends upon three factors: (1) the test's sensitivity, (2) the test's specificity, and (3) the actual frequency of the condition in the population being screened. [Slide.]

This table illustrates a common way of displaying such data. This is a simple 2-by-2 table. The left column indicates that the disease is present and the right column indicates that the disease is absent. The top row indicates that the test is positive and the bottom row indicates that the screening test is negative.

The sensitivity of a test is a measure of the test's accuracy in correctly identifying persons with the condition. It is commonly expressed as the fraction or as the percent of all persons with the condition who will have a positive test. In other words, sensitivity would be the true positives over the true positives plus the false negatives.

The specificity of a test is a measure of the test's accuracy in correctly identifying persons free of the condition. It is commonly expressed as the fraction or as the percent of all persons without

the condition who will have a negative test. In other words, the true negatives over all those patients without the disease.

The positive predictive value of a test refers to the value of a positive test in predicting the presence of the condition. This is the percent of all those with a positive test who truly have the condition. In other words, it's a row percent along the top rather than a column percent, and it is expressed as the true positives over the true positives plus the false positives.

A factor that is not commonly recognized as influencing the predictive value of a test, in addition to sensitivity and specificity, is the frequency of the condition in the population in which the test is being applied.

A brief example will illustrate how the predictive value depends upon the actual frequency of the condition in the population. [Slide.]

An electrocardiogram taken during exercise is relatively accurate, as medical tests go. It is about 95 percent sensitive and about 95 percent specific for coronary artery disease. If this test is given to 1,000 patients with angina pectoris (chest pain), a group in which the frequency of coronary artery disease is 80 percent, of the 800 persons with disease, 95 percent or 760 will have positive exercise tests. Of the 200 persons without disease 95 percent or 190 will have negative exercise tests, but 10 will have positive tests. Therefore, along the top row, the positive predictive value of the test is 760 over 760 plus 10, or 98.7 percent.

However, what if the test were applied to healthy 18 to 30 year old job applicants, a group in which the frequency of coronary artery disease is about 2 percent? [Slide.]

Again, for a hypothetical pool of 1,000 applicants, now 20 of them will have coronary artery disease—19 of those 20 will be found by the exercise test. However, with only 95 percent specificity, there will be 931 negative tests among the 980 without the disease but there will be 49 false positive tests among those people without any disease. So along the top column, if we look at the predictive value of this relatively specific test, it's 19 over 19 plus 49 or 28 percent.

This example illustrates a major problem with using diagnostic tests as screening tools. A test which may have high predictive value in a medical diagnostic situation, such as patients with chest pain, retains little predictive value if it is applied to populations where the disease frequency is low and where a significant number of individuals may be misclassified. Individuals without risk of the disease are falsely labeled as being at risk. In this example, although 95 percent of those at risk for coronary disease are identified correctly, if such a test were used as a prerequisite for employment, 72 percent of those denied employment because of a positive test would have been misclassified.

Should industry be allowed to discriminate on the basis of such screening programs? The answer may depend upon attempts to balance positive and negative social values.

The Boeing Co. might convincingly argue for using the exercise cardiogram as a prerequisite for employment of its test pilots (and I'm sure it was used for the astronauts pictured in this room). However, should Boeing be able to use the test as a prerequisite for employment of its machinists or engineers?

And if the Boeing Co. does use this screening test, even on a limited scale, what precautions should they take to protect a person who is denied employment from the adverse effects of being "labeled"?

X-ray examinations of the low back are commonly required of applicants for many jobs, including prospective policemen and firemen.

For example, in screening the majority of job applicants, most of this Nation's railroads administer a low-back X-ray examination in an attempt to ascertain the likelihood that the applicant will sustain future work-related low-back pain or injury. Many applicants are rejected for employment on the basis of the X-ray findings. The railroads apparently perceive this screening program as a cost-effective means of decreasing the incidence of compensation claims and lost workdays resulting from low-back pain or injury, and protecting particularly susceptible workers.

Low-back pain is the fourth most common complaint among adults with acute symptoms and is a common reason for time lost from work. Men and women are afflicted with equal frequency, as are white-collar workers and laborers. A retrospective survey of 250 unselected preretirees, age 62 to 65, found 60 percent had experienced low-back pain of sufficient severity to warrant medical attention at the workplace. In the United States, the annual number of lost workdays attributable to such pain is 1,400 per 1,000 workers. The incidence of the condition among industrial workers is strikingly uniform in England, the United States, Canada, Israel, and Sweden: approximately 50 cases per 1,000 workers (5 percent of the work force per year).

For railroads, as for most modern industries, low-back pain or injury is the most expensive item in disability compensation payments.

The response of the railroads to compensation claims for work-related injuries brought against them under the Federal Employers Liability Act has been summed up by the medical director of the Southern Railway System. As was mentioned, the medical departments provide the railroad industry with applicants who are as near perfect physical specimens as is possible.

In an attempt to accomplish this goal, most U.S. railroads use preemployment low-back X-ray examinations. Potential employees may be rejected on the basis of their X-ray findings alone. For example, in 1973 the Missouri Pacific Railroad gave 20,000 examinations and rejected about 40 percent of applicants on the basis of their X-ray findings.

I brought with me some low-back X-rays. These aren't real good ones. These were in the discard file. But about 3 million of these X-rays examinations are done per year at a cost of anywhere between \$50 and \$100 per examination, for an aggregate cost of somewhere between \$150 and \$300 million. Although no precise figures are available, approximately 1 million of these X-rays may be used as preemployment X-rays. Maybe one-third of the low-back X-rays being done in this country are being used in preemployment screening at a cost of up to \$60 to \$100 million.

Every low-back X-ray examination has potential health risks. These examinations are the single largest contributor to gonadal

irradiation in the United States. Gonadal shielding is often neglected for men and is difficult to accomplish for women. Furthermore, in women there is also the risk of fetal irradiation in an early, unsuspected pregnancy and fetuses exposed during X-ray examinations have as much as a doubled risk of subsequent childhood leukemia.

In addition, there are particular costs and risks of using such screening procedures in the workplace. The most obvious is the cost to the individual of being denied employment on the basis of the X-ray findings. Furthermore, problems can arise from inadequate provisions to protect the confidentiality of X-ray reports. A job applicant who is refused employment on the basis of a normal low-back X-ray examination may find it difficult or nearly impossible to get a job in another industry. In addition, many of those applicants who are acceptable for employment on the basis of a normal low-back X-ray examination are still at risk for low-back pain or injury. Both these employees and the employer may be reassured falsely by the normal X-ray findings and be less cautious in avoiding back injuries to which these employees may be prone.

One would expect that the low-back X-ray examination, a procedure with such significant costs and risks, would have its predictive value well established prior to its use in preemployment screening. The only acceptable way to establish the value of the low-back X-ray examination in predicting future low-back pain or injury would be a controlled, long-range prospective study. To my knowledge, there has never been such a study.

The only prospective study of the predictive value of these examinations had only a 4-year followup. Redfield reported that the Weyerhaeuser Co., when faced with a rapid turnover of employees and a need for more workers, hired 209 employees despite low-back X-ray findings indicating high risk. At the same time, 664 so-called normal or low risk subjects were employed. The groups were assigned similar duties. Over the 4-year followup period, the injury rate in the high risk group was 32.5 per 1,000 person-years at risk, while in the low risk control group the rate actually was nearly double, 62.3. Redfield concluded that for this population, the low-back X-ray examinations taken at the time of employment did not identify or predict the employees with the highest risk of injury, and they have discontinued the practice except for individuals of the higher age group or people with back-related histories.

Even in the clinical evaluation of a symptomatic patient with low-back pain, the low-back X-ray examination has limited usefulness. In a review of 68,000 consecutive examinations done over a 10-year period in Sweden, positive radiographic findings in patients 20 to 50 years old, unsuspected on the basis of clinical evaluation, were obtained only once per 2,500 examinations. In the majority of patients between 30 and 50 years of age, X-ray investigations of the low back reveal little that is not seen or at least suspected on clinical examination. [Slide.]

Due to its low sensitivity and specificity, the low-back X-ray examination results in both the false positive and the false negative misclassification of a significant number of potential employees. Assume that at best the examination is positive in 56 percent of persons who will have low-back pain during their lifetime—56-

percent sensitive—and in 22 percent of persons who will never have such pain—78 percent specific. Among a random group of workers, 60 percent will have low-back pain during their work life.

Here we have again a hypothetical cohort of 1,000 potential workers and 600 of those 1,000 would be expected to have low-back pain some time during their work life and 400 would not. Using the sensitivity of 56 percent and the specificity of 78 percent, we come up with the numbers in the columns. Then if we look across the first row and calculated the predictive value of a positive low-back X-ray examination in estimating future low-back pain, it would be 79 percent.

In other words, in a population in which 60 percent are already at risk for future low-back pain, a positive low-back X-ray examination may raise to 79 percent the lifetime risk of such pain. [Slide.]

If only those applicants with a negative examination are employed, 576 will get jobs, but 424 will be refused employment. Of the 424 refused employment because of a positive examination, 88 (21 percent) will never have low-back pain. Furthermore, of the 576 accepted for employment, 264 (46 percent) will have low-back pain. [Slide.]

Only about half of the people who report symptoms of low-back pain actually miss work from it. This next slide represents this fact in the same 1,000 potential workers. Of course, those who will never lose time from work because of low-back pain include those who will not have low-back pain during their lifetime, so the column on the right becomes 700 and the column on the left is 300. Using again the sensitivity and specificity to fill in the table, we see across the top that 256 over 424 or 60 percent of those who would be refused employment would never lose time from work because of back pain. Over half of those people refused employment given this sensitivity and this specificity would never lose time from work because of back pain. [Slide.]

A concern among industry is the high cost of the herniated disk case, and of the 30 percent of workers missing work for back pain, approximately 5 percent may require disk surgery. This gives an overall surgical rate of 15 per 1,000, which is close to reality. The low-back X-rays predictive value indicating who might have a risk of disk surgery is again along the top. The predictive value is about 2 percent, but again, 98 percent of those refused employment will never require disk surgery. Now we are down to this 2-percent level that previous testimony referred to.

Would it be cost efficient for the railroad, just looking at their compensation claims and the cost of disability claims for injuries requiring herniated disk surgery, to exclude employees? If you go through the cost-benefit analysis using an industrial frame of reference, the cost of the program is more than offset by the reduction in claims. Reducing the surgical rate from 15 per 1,000 down to 11.5 per 1,000, which is what would happen with this kind of program, would be enough to offset the cost of obtaining all the X-rays.

This type of accounting process is indeed being used by the industry. For example, one railroad, Southern Railway System, processed 5,800 applicants in 1 year. Ninety percent received low-back X-ray examinations for a total cost of \$235,000. The medical

director concluded that the cost of the whole X-ray program could be covered by saving six disk cases from employment.

Unfortunately, this narrow accounting considers only direct costs and benefits to industry and ignores potential negative social consequences. For example, it ignores the employment opportunities lost by applicants who are rejected for railroad jobs on the basis of X-ray findings and who may have trouble getting jobs elsewhere if word gets out about those findings. In addition, applicants who pass their X-ray examinations and who are hired by the railroad may be lulled into a false sense of security concerning future back problems. Next, there is the potential health hazard to applicants and to fetuses exposed to radiation during the examination. Finally, there is the cost of administering the examinations, which, from society's viewpoint, might better be spent in other ways, such as in supporting rehabilitation programs to help injured workers return to the work force.

Low-back X-ray examinations are used widely in the railroad industry to screen applicants for employment. Through such examinations, the railroads seek, one, to decrease the number of claims for work-related low-back injuries, two, to cut down on lost work time attributable to low-back pain or injury, and three, to protect particularly susceptible workers from job-related hazards. Although low-back X-ray examinations have low value in estimating future low-back pain or injury, the railroad industry apparently considers this screening program to be cost effective. However, the industry ignores such social costs as the potential radiation hazard of the examinations and the denial of employment to persons who are misclassified as being at increased risk for low-back pain or injury. On balance, the railroads seem to have embarked upon a screening program that has a significantly negative social value. Asymptomatic persons who are refused employment on this basis may have legal recourse under recently enacted Federal and State statutes that prohibit employment discrimination based on an actual or a perceived handicap.

[The prepared statement of Dr. Rockey follows:]

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INTRODUCTION

Pre-employment screening of job applicants for health factors that might place them at increased risk for occupational disease or injury is a widespread practice. Findings from a health history, from a physical examination and from specialized diagnostic tests often are used to assign employees to less hazardous duties, or to bar them from employment altogether.

A major factor that clearly must be taken into account is the validity or accuracy of the test used in screening. How well does that particular screening test select out those individuals who have a high probability of having or developing the disease or condition?

THE PREDICTIVE VALUE OF SCREENING TESTS

The predictive value of a screening test for a particular condition depends upon three factors: (1) the test's sensitivity, (2) the test's specificity, and (3) the actual frequency of the condition in the population being screened.

Table 1

		Disease		Total
		Present	Absent	
Screening Test	Positive	a True positives	b False positives	a + b
	Negative	c False negatives	d True negatives	c + d
	Total	a + c	b + d	a + b + c + d
Sensitivity = $\frac{a}{a + c}$				
Specificity = $\frac{d}{b + d}$				

Table 1 illustrates a common way of displaying such data. This is a simple 2 by 2 table. The left column indicates that the disease is present; the right column that the disease is absent. The top row indicates that the test is positive; the bottom row that the test is negative. You will also note the familiar terms "true positives", "false negatives", false positives", and "true negatives".

Sensitivity of a test

The sensitivity of a test is a measure of the test's ^{#7} accuracy in correctly identifying persons with the condition. It is commonly expressed as the fraction or as the percent of all persons with the condition who will have a positive test, or:

$$\frac{\text{true positives}}{\text{true positives} + \text{false negatives}}$$

Specificity of a test

The specificity of a test is a measure of the test's accuracy in correctly identifying persons free of the condition. It is commonly expressed as the fraction or as the percent of all persons without the condition who will have a negative test (true negatives), or:

$$\frac{\text{true negatives}}{\text{true negatives} + \text{false positives}}$$

Predictive Value of a test

The (positive) predictive value of a test refers to the value of a positive test in predicting the presence of the condition. This is the percent of all those with a positive test who truly have the condition, or:

$$\frac{\text{true positives}}{\text{true positives} + \text{false positives}}$$

A factor that is not commonly recognized as influencing the predictive value of a test, in addition to sensitivity and specificity, is the frequency of the condition in the population in which the test is being applied.

A brief example will illustrate how the predictive value depends upon the actual frequency of the condition in the population. An electrocardiogram (ECG) taken during exercise is relatively accurate, as medical tests go. It is about 95 percent sensitive

and about 95 percent specific for coronary artery disease. If this test is given to 1,000 patients with angina pectoris (chest pain), a group in which the frequency of coronary artery disease is 80 percent, of the 800 persons with disease, 95 percent or 760 will have positive exercise tests. Of the 200 persons without disease, 95 percent or 190 will have negative exercise tests, but 10 will have positive tests. Therefore, the (positive) predictive value of the test is $760 / (760 + 10)$ or 98.7 percent.

Table 2
Coronary Artery Disease

Exercise Electrocardiogram (ECG)	Coronary Artery Disease		Total
	Present	Absent	
Positive	760	10	770
Negative	40	190	230
Total	800	200	1000

$$\text{Predictive Value} = \frac{760}{760 + 10} = 98.7\%$$

However, what if the test were applied to healthy eighteen to thirty-year-old job applicants, a group in which the frequency of coronary artery disease is about 2 percent? If 1,000 applicants were screened, 19 of the 20 (95 percent) with disease would have positive tests. Of the 980 applicants without disease, 931 (95 percent) would have negative tests, but 49 would have positive tests. Therefore, the predictive value of the test is $19 / (19 + 49)$ or 28 percent. This means that only 28 percent of those with

a positive test actually have coronary artery disease (true positives), and the other 72 percent with a positive test are free of the disease (false positives).

Table 3

		Coronary Artery Disease		
		Present	Absent	Total
Exercise Electrocardiogram (ECG)	Positive	19	49	68
	Negative	1	931	932
	Total	20	980	1000

$$\text{Predictive Value} = \frac{19}{19 + 49} = 28\%$$

This example illustrates a major problem with using diagnostic tests as screening tools. A test which may have high predictive value in a medical diagnostic situation, such as patients with chest pain, retains little predictive value if it is applied to populations where the disease frequency is low and where a significant number of individuals may be misclassified. Individuals without risk of the disease are falsely labeled as being at risk. In this example, although 95% of those at risk for coronary disease are identified correctly, if such a test were used as a prerequisite for employment, 72 percent of those denied employment because of a positive test would have been misclassified.

Should industry be allowed to discriminate on the basis of such screening programs? The answer may depend upon attempts to balance positive and negative social values.

The Boeing Company might convincingly argue for using the exercise cardiogram as a prerequisite for employment of its test pilots. However, should it be able to use the test as a prerequisite for employment of its machinists or engineers?

X And if the Boeing Company does use this screening test, even on a limited scale, what precautions should they take to protect a person who is denied employment from the adverse effects of being "labeled"?

DISCRIMINATORY ASPECTS PRE-EMPLOYMENT SCREENING:
LOW-BACK X-RAY EXAMINATIONS IN THE RAILROAD INDUSTRY

X-ray examinations of the low back are commonly required of applicants for many jobs including prospective policemen and firemen.

For example, in screening the majority of job applicants, most of this nation's railroads administer a low-back X-ray examination in an attempt to ascertain the likelihood that the applicant will sustain future work-related low-back pain or injury. Many applicants are rejected for employment on the basis of the X-ray findings. The railroads apparently perceive this screening program as a cost-effective means of decreasing the incidence of compensation claims and lost workdays resulting from low-back pain or injury, and protecting particularly susceptible workers.

Low-Back Pain and Injury: The Problem and the Railroads'Response:

Low-back pain is the fourth most common complaint among adults with acute symptoms and is a common reason for time lost from work. Men and women are afflicted with equal frequency, as are white collar workers and laborers. A retrospective survey of 250 unselected pre-retirees, age sixty-two to sixty-five, found 60 percent had experienced low-back pain of sufficient severity to warrant medical attention at the work place. In the United States, the annual number of lost workdays attributable to such pain is 1,400 per 1,000 workers. The incidence of the condition among industrial workers is strikingly uniform in England, the United States, Canada, Israel, and Sweden: approximately fifty cases per 1,000 workers (5 percent of the work force per year).

For railroads, as for most modern industries, low-back pain or injury is the most expensive item in disability compensation payments. (In 1971, of the ninety American railroads, sixty-five reported their claims experience to the Claims Index Bureau of the association of American Railroads. There were about 800 low-back injury cases for which settlements and awards totaled over \$18,000,000. About 300 of the 800 cases involved ruptured intervertebral discs. The "disc" cases cost the railroads about \$9,500,000 or an average of about \$33,000 per case. Back cases not involving a ruptured disc cost them about \$18,000 per case.)

The response of the railroads to compensation claims for work related injuries brought against them under the Federal Employer's

Liability Act has been summed up by the medical director of the Southern Railway System:

(I)t . . . behooves the railroad industry to insure, through its medical department(s), that its employees are in top-notch physical condition and, also, that the medical department(s) provide the railroad industry with applicants who are as near perfect physical specimens as is possible for us to find . . .

. . . (I)n the face of staggering claims and settlements, we feel we must do everything possible to exclude the potentially serious back injury. |

In an attempt to accomplish this goal, most U.S. railroads use pre-employment low-back X-ray examinations. Potential employees may be rejected on the basis of their X-ray findings alone. For example, in 1973 the Missouri Pacific Railroad gave 20,000 examinations and rejected about 40 percent of applicants on the basis of their X-ray findings. (C)

Are The Social Costs and Individual Risks Justified?

(Public Health Service figures indicate that 3,000,000 low-back X-ray examinations are performed each year, at an aggregate cost of \$150 million. Although no precise figures are available, it is estimated that as many as 1,200,000 of these are pre-employment examinations costing as much as \$60 million.

Every low-back X-ray examination involves a potential health risk. These examinations constitute the largest single contribu-

tor to gonadal irradiation in the United States. Gonadal shielding often is neglected for men and is difficult to accomplish for women. Furthermore, in women there is also the risk of fetal irradiation in an early, unsuspected pregnancy. With more women entering the work force and being subjected to screening, this problem is likely to increase. Fetuses exposed during diagnostic X-ray examinations have as much as a doubled risk of subsequent childhood leukemia; for highly susceptible fetuses, the risk may be higher.

In addition, particular costs and risks arise from the use of these examinations for pre-employment screening. The most obvious is the cost to the individual of being denied employment on the basis of the X-ray findings.)² Furthermore, problems can arise from inadequate provisions to protect the confidentiality of X-ray reports. A job applicant who is refused employment on the basis of a normal low-back X-ray examination may find it difficult or nearly impossible to get a job in another industry. In addition, many of those applicants who are acceptable for employment on the basis of a normal low-back X-ray examination are still at risk for low-back pain or injury. Both these employees and the railroad ^{employer} may be reassured falsely by the normal X-ray findings and be less cautious in avoiding back injuries to which these employees may be prone.

The Low Predictive Value of Low Back X-rays

One would expect that the low-back X-ray examination, a procedure with such significant costs and risks, would have its predictive

value well established prior to its use in pre-employment screening. The only acceptable way to establish the value of the low-back X-ray examination in predicting future low-back pain or injury would be a controlled, long-range prospective study. To my knowledge, there has never been such a study.

The only prospective study of the predictive value of these examinations had only a four year follow up. Redfield reported that the Weyerhaeuser company, when faced with a rapid turnover of employees and a need for more workers, hired 209 employees despite low-back X-ray findings indicating "high-risk". At the same time, 664 so-called normal or "low-risk" subjects were employed. The groups were assigned similar duties. Over the four-year follow-up period, the injury rate in the "high-risk" group was 32.5 per 1,000 person-years at risk, while in the "low-risk" control group the rate actually was nearly double, 62.3. Redfield concluded that for this population, the low-back X-ray examinations taken at the time of employment did not identify or predict the employees with the highest risk of injury.³

(Increasingly, it is becoming recognized that even in the clinical evaluation of a symptomatic patient with low-back pain, the low-back X-ray examination has limited usefulness. In a review of 68,000 consecutive examinations done over a ten-year period in Sweden, positive radiographic findings in patients twenty to fifty years old, unsuspected on the basis of clinical evaluation, were obtained only once per 2,500 examinations. In the majority of patients between 30 and 50 years of age, X-ray investigations

of the low back reveal little that is not seen or at least suspected on clinical examination.

How Misclassification Occurs

Due to its low sensitivity and specificity, the low-back X-ray examination results in both the false positive and the false negative misclassification of a significant number of potential employees. Assume that at best the examination is positive in 56 percent of persons who will have low-back pain during their life-time (56 percent sensitive) and in 22 percent of persons who will never have such pain (78 percent specific).^{*} Among a random group of workers, 60 percent will have low-back pain during their work life. Table 4 represents a hypothetical cohort of 1,000 potential workers.

^{*} This assumption is based upon the fact that the only X-ray findings consistently correlated with low-back pain are degenerative disc changes, and these percentages reflect the prevalence of such findings in persons who have and have not had low-back pain. However, it must be stressed that these percentages overestimate the sensitivity and specificity of the examinations, because they ignore the fact that X-ray evidence of degenerative discs is rare under the age of 25 years, increases with advancing age, and often appears after the first bout of low-back pain.

Table 4

	Will have low-back pain during lifetime	Will not have low- back pain during lifetime	Total
Will have positive low-back X-ray exam	336 (true positives)	88 (false positives)	424
Will have negative low-back X-ray exam	264 (false negatives)	312 (true negatives)	576
Total	600	400	1,000

The predictive values of a positive low-back X-ray examination in estimating future low-back pain is 336 / 424 (79 percent). In other words, in a population in which 60 percent are already at risk for future low-back pain, a positive low-back X-ray exam may raise to 79 percent the lifetime risk of such pain. If only those applicants with a negative examination are employed, 576 will get jobs, but 424 will be refused employment. Of the 424 refused employment because of a positive examination, 88 (21 percent) will never have low-back pain. Furthermore, of the 576 accepted for employment, 264 (46 percent) will have low-back pain.

Only half of the persons who report symptoms of low-back pain will miss any work because of it. Table 5 represents this fact in the same 1,000 potential workers. (Of course, those who will never lose time from work because of low-back pain include those who will not have low-back pain during their lifetime.)

Table 5

	Will have low-back pain and lose time from work	Will never lose time from work because of low-back pain	Total
Will have positive low-back X-ray exam	168 (true positives)	256 (false positives)	424
Will have negative low-back X-ray exam	132 (false negatives)	444 (true negatives)	576
Total	300	700	1,000

Among the 30 percent of employees with low-back pain severe enough to cause them to miss time from work a conservative estimate of the number of persons with severe low-back pain requiring disc surgery is 5 percent, giving an overall surgical rate of 1.5 percent.

Table 6

	Will have disc surgery	Will not have disc surgery	Total
Will have positive low-back X-ray exam	8.4 (true positives)	416 (false positives)	424
Will have negative low-back X-ray exam	6.6 (false negatives)	569 (true negatives)	576
Total	15.0	985	1,000

At this rate of surgery, the predictive value of a positive examination is 8.4 / 424 (2 percent); in other words, 416 (98 percent) of the 424 persons refused employment would never require back surgery.

An Evaluation of the Railroads' Policy

If low-back X-ray examinations misclassify such a high percentage of job applicants as being at increased risk for future low-back pain or injury, why does the railroad industry persist in using them? Apparently, from the industry's vantage point only direct financial considerations must be taken into account because of the large number of high quality job applicants. Therefore, the industry may perceive that the cost of this relatively poor test, of low predictive value, is the only relevant cost and is still more than offset by the reduction in lost work days and costly claims.

Of particular concern to the railroad industry is the cost of low-back pain cases requiring disc surgery, because these workers usually are thirty to fifty years old, and they may develop long-term disability. At the 1.5 percent overall surgical rate (Table 3), if screening could reduce the rate of disc surgery from 15 per 1,000 to 11.5 per 1,000 (6.6/576), this might "save" 3.5 disc surgery cases per 1,000 employees. In order to find 1,000 "better risk" employees, the railroad would have to screen 1,736 applicants. At fifty dollars per examination, the cost of the X-ray program for these applicants would be about \$87,000. Claims

for low-back injury cases requiring disc surgery cost the railroads about \$33,000 per case in 1971. Therefore, reducing disc surgery cases by 3.5 per 1,000 employees could save the industry \$115,000.)

This type of accounting process is indeed being used by the industry. For example, one railroad, Southern Railway System, processed 5,800 applicants in one year. Ninety percent received low-back X-ray exams for a total cost of \$235,000. The medical director concluded that the cost of the whole X-ray program could be covered by saving six disc cases from employment.

Unfortunately, this narrow accounting considers only direct costs and benefits to industry and ignores potential negative social consequences. For example, it ignores the employment opportunities lost by applicants who are rejected for railroad jobs on the basis of X-ray findings and who may have trouble getting jobs elsewhere if "word gets out" about those findings. In addition, applicants who "pass" their X-ray examinations and who are hired by the railroad may be lulled into a false sense of security concerning future back problems. Next, there is the potential health hazard to applicants and to fetuses exposed to radiation during the examination. Finally, there is the cost of administering the examinations, which, from society's viewpoint, might better be spent in other ways, such as in supporting rehabilitation programs to help injured workers return to the work force.

SUMMARY

Low-back X-ray examinations are used widely in the railroad industry to screen applicants for employment. Through such examinations, the railroads seek (1) to decrease the number of claims for work-related low-back injuries, (2) to cut down on lost work time attributable to low-back pain or injury, and (3) to protect particularly susceptible workers from job-related hazards. Although low-back X-ray examinations have low value in estimating future low-back pain or injury, the railroad industry apparently considers this screening program to be cost-effective. However, the industry ignores such social costs as the potential radiation hazard of the examinations and the denial of employment to persons who are misclassified as being at increased risk for low-back pain or injury. On balance, the railroads seem to have embarked upon a screening program that has a significantly negative social value. Asymptomatic persons who are refused employment on this basis may have legal recourse under recently enacted federal and state statutes that prohibit employment discrimination based on an actual or a perceived handicap.

Mr. GORE. Thank you very much. I appreciate that. It's your conclusion that preemployment back X-rays should not be used; is that a fair summary?

Dr. ROCKEY. I think that the practice is widely abused.

Mr. GORE. And you worry about the discriminatory effect of the program as it's currently applied to prospective employees who are turned down when the predictive value is as low as it is?

Dr. ROCKEY. Yes, that's my major concern. I think that if the program were used after the decision had been made to hire the employee—an employee was already in the fold, so to speak—and then the X-ray was used as part of a placement procedure or part of a procedure to get the person into the best job, then it might be useful. But I think that the railroad industry has barred employment of these individuals based upon a medical test. However, I understand why they have done that, the FELA is especially repressive.

Mr. GORE. What's your opinion of the 2-percent or 5-percent hypothetical?

Dr. ROCKEY. I think that you have to look at it in the context of the social values that are being balanced. It's like the example that I used with the coronary artery disease. I don't think we would have wanted the pilot of the Space Shuttle to have any risk of coronary artery disease, but I think that if you're employing someone in your office building it's not your responsibility to determine whether or not they have coronary disease and discriminate in employment. So it's shades of gray.

Mr. GORE. Do you agree with my conclusion that the genetic screening potential is going to make these issues much larger than they now appear?

Dr. ROCKEY. Yes, I do. As a matter of fact, I think that we know enough now about some of the risks associated with some of the HLA antigens that I'm surprised some of them haven't been picked up by industry.

If I could just show a few more slides related to the HLA antigen. If we make the following assumptions about the histocompatibility antigen which used to be called B-27 but is now called HLA-27. [Slide.]

Slide 15

ASSUMPTIONS

The histocompatibility antigen B-27 occurs in about 7 percent of the healthy white population.

About 95 percent of patients with ankylosing spondylitis are B-27 positive.

The presence of B-27 predicts a risk of ankylosing spondylitis of 20 to 25 percent.

It occurs in about 27 percent of the healthy white population. It's variable in different populations. And about 95 percent of the patients with ankylosing spondylitis are positive for HLA-27 and the presence of HLA 27 predicts a risk of ankylosing spondylitis of 20 to 25 percent. Those assumptions are based upon several different studies. We would generate a similar table to what we have looked at before in the next slide. [Slides.]

Slide 16

ANKYLOSING SPONDYLITIS

	Will have ankylosing spondylitis	Will not have ankylosing spondylitis	Total
Will have positive HLA-B-27	14	56	70
Will have negative HLA-B-27	1	929	930
Total	15	985	1,000

ASSUMPTIONS

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About 95 percent of patients with ankylosing spondylitis are B-27 positive.

The presence of B-27 predicts a risk of ankylosing spondylitis of 20 to 25 percent.

Slide 17

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Will have positive HLA-B-27	14	56	70
Will have negative HLA-B-27	1	929	930
Total	15	985	1,000

RESULTS

75 to 100 percent of those refused employment would never have the disease.

Slide 18

INDUSTRY "COST-BENEFIT" ANALYSIS

1000 test at \$50 per test-\$50,000-"cost" to industry.

14 cases at \$10,000 compensation per case-\$140,000 "benefit" to industry.

If the disease prevalence is about 15 out of 1,000, HLA-27 screening would correctly identify 14 of those 15 individuals. That's the sensitivity of the test.

Mr. GORE. And this is a back problem of a kind that would be—

Dr. ROCKEY. Ankylosing spondylitis is a medical condition where the back fuses. It's quite different than what was being referred to. It's not the garden variety back problem that affects 60 percent. It affects only about 1.5 percent of the population. But again, that 1.5 percent really develops severe back disability.

Now if you look at what would happen if this test was used for preemployment screening. Because of the false positives, if we used this to exclude people from the workplace, we would exclude 70 people in order to get the 14 that would be at high risk and we would have misclassified 56. We would have told those 56 individuals that they were at risk for a disease that they will never get.

Mr. GORE. Well, I draw two conclusions from your example. First of all, it supports my suspicion that the potential for HLA antigen screening is immense because it is more predictive. Even in the specific example of railroad employment which we chose not for these reasons, but even here it's more predictive than the tests that are now underway. Would you agree with that?

Dr. ROCKEY. I would agree with that. If it were possible to genetically classify individuals and find out which ones were at risk for the early degeneration of the disks, that obviously would be the predictor that people would be interested in.

Mr. GORE. And my conclusion again is simply that that confirms my suspicion or tends to confirm my suspicion of the fantastic potential of this new technology, but my second conclusion is that in the confines of this specific example we still see present the potential for discrimination against healthy people who may not have the condition at all and discrimination against people who are classified inaccurately. So it's quite troubling.

I'm not sure how we're going to solve the problem, but it's good to get a start on it before it gets out of hand.

I'd like to thank you for your testimony here today. We are going to move on to our last witness, but I appreciate very much your taking the time to come and share your views with us and your slides particularly. Did you have anything to add before we move on?

Dr. ROCKEY. No. I think that the one point I wish to emphasize is that our best tests have sensitivities and specificities in the range of 95 to 99 percent and when the disease prevalence is low, even excellent tests will always result in a misclassification of individuals.

Mr. GORE. OK. Well, thank you very much. We certainly appreciate it.

Our final witness today in the first day of this 2-day hearing is Dr. Gilbert Omenn from the Brookings Institution and the University of Washington, Seattle. Dr. Omenn, we are pleased to welcome you back to the subcommittee. We appreciate your coming again and, without objection, your testimony will be put into the record in full and we invite you to proceed as you wish.

STATEMENT OF GILBERT OMENN, BROOKINGS INSTITUTION

Dr. OMENN. Thank you, Congressman Gore. In fact, it's a hectic morning. Two floors down from here there's a clean air hearing in which I'm also speaking.

I will present the highlights of the written testimony.

I think this hearing has generated quite a fascinating discussion of the state of the art of diagnostic screening tests and also the need to be rigorous about assessing these kinds of medical technologies in any applications to the workplace.

There are three classes of reasons for screening in the workplace. They are to protect the worker, to support the regulatory process that's required under the Occupational Safety and Health Act, and to reduce the employer's liability. All of those are valid and necessary.

Despite the reasons given above and despite continued costly screening procedures, preplacement evaluation has fallen into con-

siderable disrepute. Its benefit to either the employee or the employer has been challenged. In high-turnover, low-hazard industries, there may be a poor benefit-cost ratio. Some industries have approached this problem by reducing costs through use of paramedical personnel, especially nurses, to do the evaluations, which is generally quite satisfactory. Another reason for the disrepute is the often poor quality or lack of specific relevance of the evaluation and tests to the particular hazards in a given workplace. A third reason is the disparity in interpretation of findings by physicians or other health professionals.

Finally, there is the recognition that highly motivated individuals can often overcome seemingly serious physical handicaps. Laws to assist the handicapped have been beneficial.

I will direct the bulk of my comments to the specific area of genetic differences. There can be no doubt that people differ remarkably in many body functions and in the underlying genes and gene functions. Studies have been done for many years of individual variation in blood groups, plasma proteins, red blood cell enzymes, histocompatibility antigens, and now DNA sequences. At all levels of investigation, very significant variation has been demonstrated.

Advances in genetics have been truly remarkable, and there's considerable interest in the application to medicine.

There have been several kinds of genetic screening carried out. We should be explicit in distinguishing screening tests of patients, such as persons who already have back problems, from genetic screening of unsuspecting individuals in the population. The problem of informed consent is severe in the general screening situation. We have learned a lot, somewhat to our chagrin, from population screening for phenylketonuria [PKU] and sickle cell disease and sickle cell trait.

One word about PKU has to be mentioned. I can assure you that seeing patients who are identified by screening as having metabolic defects of PKU in the early days of life and put on a special diet and grow up to be normal instead of being institutionalized for life with the mentally retarded, generates great pride in the technology that enables us to do that.

However, not too many people are aware that when the PKU screening was introduced—and the screening test here has 98 percent sensitivity and 99.9 percent specificity—the result was that the incidence of the disease apparently doubled. Twice as many newborn people were found with high levels in the blood and were stamped as PKU as were expected previously from counting bodies. That seemed to indicate that we were missing them before. Wrong. We were misdiagnosing an equal number to the number properly diagnosed as PKU. Now we understand that the levels may be high in the blood and in the urine due to other reasons which are generally harmless. All of these are interesting scientifically, but in practice a lot of children were put on the PKU diet until we learned that we have to retest them after 3 months. Tragically, there were a few among those who had a variant of the enzyme which requires higher levels of phenylalanine; those kids do badly on a low phenylalanine diet. So a few kids suffered mental and

physical retardation of growth as a result of the misdiagnosis. Thus, even in one of our very best examples there were problems.

In the case of sickle cell screening there's a much worse situation. There was confusion between sickle cell disease, which is a serious anemia, and sickle cell trait. Eight percent of the American black population has sickle cell trait. Unfortunately, some people confused the disease and the trait and many case reports appeared from good physicians identifying the joint occurrence of sickle cell trait and kidney infections, problems in pregnancy, or any of a host of complications. It's widely stated that people with sickle cell trait are predisposed to have these various conditions.

The only way that can be assessed is to do a population-based study, not case by case. You start with the recognition that 8 percent of the black population has sickle cell trait and a certain percentage of the black population has these other specific diseases or symptoms. You must find out if there is a joint occurrence which is greater than chance, including the bias of ascertainment that you're following the patients closely, which is very important.

After nearly all of those associations melted away, the only one that was left and has clear implications for our discussion today is the well-acknowledged fact that red blood cells containing sickle cell hemoglobin will distort and sickle if you put the cells in low oxygen. It was deduced and it is true that if you put people at very high altitude or airplanes lose their pressurization that persons with sickle cell trait would be at risk to have sickling of their cells, with pain and possibly more severe reactions to the pain or damage.

As a result, the Air Force had a policy that no black American who had sickle cell trait would be admitted to the Air Force Academy and no black with sickle cell trait would be permitted to take pilot training, whether they went to the Air Force Academy or not. That was challenged with the same kind of logic that was presented here by Dr. Rockey and with similar lack of success until, after 10 years, the Air Force last year was overruled by the Department of Defense and instructed to admit blacks with sickle cell trait to the Air Force Academy and to pilot training programs. The Air Force will carry out the kind of medical surveillance which we think would be appropriate, especially in this case where there's uncertainty and need for information.

This is an important example, one which was fought about in the Federal Government for quite a period of time with experts from both sides and from outside the Government. Unfortunately, these experts and policy officials were making decisions in the absence of evidence. For the future, it will be very important to have a systematic way of gaining information, asking the questions you're asking now and gaining the evidence so we can make decisions about what kind of screening truly protects workers and potential workers and which kind of screening is so marginal that it should not be utilized.

In addition to sickle cell trait, another test that has been described in the literature and utilized is the serum antitrypsin deficiency test for predisposition to chronic pulmonary disease. Pulmonary emphysema is characterized anatomically by destruction of the alveolar air spaces of the lung. The mechanism appears to be

proteolytic enzyme damage by enzymes released from white blood cells and macrophages in the lungs. Severe deficiency of the protective protein alpha-1 antitrypsin occurs in about one in a few thousand people. These people clearly are predisposed to pulmonary emphysema, especially if they smoke. A good many of them do not develop emphysema.

However, the issue for screening is not the one in a few thousand but the carriers, who are much more frequent, constituting 2 to 4 percent of the population. Many studies have been done to ascertain whether these carriers, with about half the normal level of protective protein, are at significantly higher risk of developing chronic lung disease. The best you can say is that the answer is controversial and uncertain, because the differences are small, depending upon which patients have been studied, exactly how the tests were done, whether there were concurrent infections, how much smoking, (a synergistic factor,) contributed.

The results of different studies differ and the fact is that the effects are small. There is no basis for utilizing this test, in my opinion, at this time for industrial screening. To my knowledge, the few companies that did use this screening test when it was new have stopped.

Another potentially useful test measures glucose-6-phosphate dehydrogenase (G-6-PD) deficiency in red blood cells. This X-linked genetic abnormality predisposes affected males to hemolytic crisis, which is a breakdown of red blood cells with resulting anemia. Many drugs and other nondrug chemicals in the environment are oxidizing compounds which can precipitate acute anemia in such persons.

This is an example of special populations because, as was heard before, genetic traits vary in their frequency in different geographic and ethnic populations. In this case there are two very common abnormal variants, one in blacks and one in Mediterranean people. In both cases we have good evidence to believe that years ago when malaria was a leading worldwide cause of death the ancestors of these people survived with some advantage because of the glucose-6-phosphate dehydrogenase deficiency. Now that malaria has been eliminated in places like Greece and Sardinia and elsewhere, the frequency of this gene is declining. Most people who have this deficiency are perfectly fine. The major risk is that they will be given a drug which triggers a breakdown of their red blood cells or that they might be exposed to a chemical in their workplace which would do the same thing.

Unfortunately, although the drug-induced anemia due to G6PD deficiency anemia has been studied extensively for almost 30 years, there have been no systematic studies of risks from occupational exposures. None of the chemical classes known to trigger the reaction has been investigated with regard to whether workers of Mediterranean or of West African ancestry would be at special risk. A few companies did do screening in a desultory and information-gathering fashion—Dow and Du Pont—but to my knowledge, nobody was excluded from jobs and there was no basis in terms of solid results for them to do so.

The only examples of occupational hazard for G-6-PD-deficient men are three cases reported in 1975 from the workers' sick fund

research section of Iraqi Jews working in Israel in a TNT plant. The workers were dealing with nitroamino and nitroaromatic compounds and suffered acute and severe anemia. Two more unpublished cases have been noted in the same factory, I have been told. There's research work to be done, but it is premature to consider routine screening.

Finally, there's a very interesting area of dermatology. This hasn't been much discussed today, but 70 percent of the industrial claims for occupational disease are for dermatological conditions. Many of these have to do with contact dermatitis. There are tests for some of these, though predictive values have seldom been ascertained. Tests would fit into a surveillance program. I believe there is some use made of these tests, but no organized research.

Before passing on to the policy issues, let me mention that there are two newly discovered genetic traits which may interest you and deserve considerable research investigation in the occupational setting.

The first is the paraoxonase polymorphism. This plasma enzyme inactivates parathion and paraoxon and probably also malathion. Parathion is one of the commonly used neurotoxic organophosphorous pesticides. About half of the population, both Caucasians and blacks, have a low-activity form of the paraoxonase enzyme, with only one-third to one-sixth of the activity of those with the high-activity form of the enzyme. A single gene determines high or low activity. The population genetics and biochemistry of the enzyme variation are being worked out. My colleagues and I think it is appropriate to carry out research investigations to see whether this particular metabolic variation accounts for differences in susceptibility to pesticide poisonings in occupational settings and for the general population. The place to start is with the applicators and mixers whose exposures are the highest. In my own State of Washington, there have been some 167 claims paid by the State to covered workers for pesticide poisonings in the past 5 years.

The second involves the carbon oxidation mechanisms controlled by a single gene. Debrisoquine and sparteine are useful test drugs to reveal this genetic difference. What's interesting here is that several different drugs, which require different enzyme activities for their inactivation, are either very extensively metabolized or very poorly metabolized by the same system. The difference here is not plus or minus 5 percent. The difference here is 20,000-fold. Nine percent of the population essentially don't metabolize the drug chemicals, while the other people have high activity. The poor metabolizers risk serious side effects from the usual doses of these drugs.

What makes this genetic X-ray relevant for today's hearing is that these enzymes are part of the microsomal liver drug metabolizing enzyme systems, which also activate and inactivate environmental chemicals. One of these is aflatoxin, which is a cause of liver cancer in West Africa. The hypothesis here would be that those who have poor oxidizing activity would be less capable of activating the aflatoxin to its carcinogenic form. What was found in Nigeria recently is consistent with that hypothesis; there was a significantly lower frequency of poor metabolizers among liver cancer patients, compared with the general population. Other pro-

carcinogens must be activated in the liver. So poor metabolizers may be relatively resistant to other environmental cancer inducing agents as well. There's work to be done both in vitro and in vivo to characterize this system. It is likely that cytochrome P450 structures or matrix are involved, affecting several different enzymes activities.

This debrisoquine-sparteine oxidation system is of interest also because a related group of metabolizing enzymes activates the aryl hydrocarbons in cigarette smoke and in air pollution. These aryl hydrocarbons are among the most important potential carcinogens in cigarette smoking and air pollution. Eight years ago there was a published report that individual humans tested with blood samples for lymphocyte differed strikingly in their aryl hydrocarbon hydroxylase activity in blood lymphocyte tested in vitro for induction by these outside chemicals. It was postulated that those who were higher inducers should be the ones who would activate more of the carcinogenic form and therefore the ones who got lung cancer from cigarette smoke. A second study was then published showing that the majority of lung cancer patients had the high-inducing form, compared with only 9 percent frequency in the general population. Unfortunately, nobody has been able to reproduce the method and it's been in disrepute for sometime. The genetic trait which I mentioned above may be a new way of getting at this 8-year-old controversy.

If a useful test could be developed, for example, which subdivides smokers into those with very high risk and those with less risk, I suspect that would be of quite general interest and of tremendous interest in the workplace.

With regard to cigarette smoking, I feel that it would be irresponsible to have a discussion of hypersusceptible workers without focusing on the problem of smoking. The Surgeon General's reports of 1964 and 1979, a NIOSH report and many other reports emphasize the severe exacerbation of occupational hazards by smoking. These effects are due to six types of mechanical:

First, certain toxic agents in the workplace also occur in tobacco products or smoke; thus, smoking increases exposure. More than 40 different toxic compounds have been found, including carbon monoxide, cadmium and many others.

Second, workplace chemicals may be transformed into more harmful agents by burning tobacco. An example is polymer fume fever. The temperature of burning tobacco in a cigarette is about 1,600 degrees fahrenheit.

Third, tobacco products may serve as vectors by becoming contaminated with toxic agents from the workplace, facilitating entry into the body by inhalation, ingestion, or skin absorption.

Fourth, the effects of smoking may be additive with effects of agents in the workplace, such as chlorine, cotton dust, coal dust or beta radiation.

Fifth, smoking may act synergistically with effects of agents in the workplace—asbestos, gold mine exposures, rubber industry exposures, radon radiation products.

Sixth, smoking may contribute to accidents in the workplace—loss of attention, preoccupation of the hand, irritation of the eyes, cough, fires.

In delivering a notable memorial lecture in London, a well-known British occupational physician—Elmes—analyzed the relative importance of cigarette smoking in occupational lung disease. He concluded for the notorious coal and iron and steel industries in Britain and Germany that conditions have now been improved sufficiently that the dust exposures contribute much less to morbidity or mortality than do the workers' smoking habit. That doesn't mean we should do less about the dust exposures, but it means we are missing a major exposure in their risks.

These are issues that deserve research, as I've mentioned over and over. Some say you can't do this kind of research, but I say that's not so. I can cite the excellent model of good relations among unions, management, and academic researchers in the form of the three-way arrangement of investigators at the Harvard School of Public Health, the United Rubber, Cork, Linoleum and Plastic Workers of America, and the B. F. Goodrich, Armstrong Rubber, and Mansfield Tire & Rubber Cos. I think this is a good example. There is full participation by representatives of management and union in the decisions of what the researchers ought to be doing and what should be done with their information.

Less developed but with significant potential, is an activity at the University of Washington in the industrial hygiene program supported by the State department of labor and industries, with an oversight committee that includes representatives of the State labor council and of companies. In April, I'm moving back to Seattle to become chairman of that department of environmental health.

I am persuaded that explicit arrangements can be made to permit research investigations and to specify the uses of data and access to data. It is essential that all participants recognize the differences between open-minded research and the potential subsequent application of tests, if validated, for routine screening and surveillance. The Harvard and University of Washington examples provide for workers' consent for studies of safety and health risks, although it is not clear how much involvement individual workers actually have or feel.

Now the last few minutes I'll spend on your specific questions. I believe that the extensive medical histories and physical and laboratory examinations carried out on workers at present represent a substantial investment, oftentimes with the best of intentions, sometimes with sound basis, but too often without a validated scientific base or adequate relevance to particular exposures. I don't think I need to add comments about the low back X-ray. That's been adequately ventilated by the previous speakers. I'm sympathetic to the problems of the railroad industry, because as physicians we all face the problem of the individual patient and the notion of "couldn't you have done something for me, Doc" However, now more and more we're hearing questions like, "What did you do to me, Doc; and why? Wouldn't it have been better if you had left me alone?" So this cuts both ways. I think we have discussed this adequately.

I do want to add a comment about the B-27. I have published on the HLA testing and its underlying genetics. I support what Dr. Rockey showed with one proviso. That is, there's a disagreement on

the frequency of spondylitis, depending on the criteria for making the diagnosis. Even though individuals with B-27 have roughly 200 times higher risk of ankylosing spondylitis than do people without B-27, the absolute risk is still low—about 5 percent for symptoms that are clearcut, perhaps up to 20 percent for suggestive symptoms. Thus, 80 to 95 percent of workers with B-27 would not have and would not be expected to develop ankylosing spondylitis. Early diagnosis and treatment may not even change the course of the disease. Not only would a positive B-27 test not be basis for excluding workers, but also this lab test would miss the rare patient with some remediable back condition. So the B-27 is not to be recommended for screening, in my opinion.

I can suggest some criteria for the development of any research results into potential tests. First, the prevalence of the predisposing trait must be sufficient to be detected in usual worker populations; usually this will mean at least 5 percent prevalence but "sufficient" will depend upon the reliability and cost of testing and the relative risk and its consequences.

Second, the prevalence in various subgroups in the population should be determined, since genetic traits often occur with differing prevalence in different ethnic or geographic groups.

Third, the relative risk for a significant adverse outcome must be at least three—risk for those with the trait compared with those lacking the trait—based upon experience with relative risks for histocompatibility types associated with various diseases; preferably the relative risk should exceed 10 times, so as to enhance the likelihood that the particular tested predisposition is putting those workers at significantly higher risks than other presumed but non-testable predispositions within the overall population.

Fourth, the test itself must be reliable, inexpensive, and well characterized for false positives and false negatives.

Fifth, there must be a clear understanding with management and workers about how test results are to be utilized and what actions might be based upon the results.

I would like to suggest as we move, as you're predicting, to utilizing some genetic tests in the next decade that we pick the ones that are clearly useful and not marginal ones about which we generate nothing more than more controversy.

Your question about screening serving as a substitute for improvements in workplace quality is central to the labor/management tension over responsibility for workplace safety. In common law and numerous labor negotiations, it is clear that the primary responsibility lies with the employer. As Elmes has stressed, substantial improvements in work conditions in the coal, iron and steel, asbestos, and slate industries have had far less overall results than would be feasible if reduction of smoking had accompanied these environmental changes—not substituted for but accompanied these environmental changes. It's my impression that the Johns-Mansville Co. policy to assist workers in certain jobs to stop smoking or switch jobs has been supported in arbitration rulings primarily because the company made very substantial investments in reducing exposures and did actually control most of the asbestos dust exposures.

Mr. GORE. If I may interrupt you there, is it true that they also tried to require a no smoking policy in the workplace and were overruled on that?

Dr. OMENN. My understanding is that Dr. Paul Kotin, who is a former head of NIOSH and was medical director and senior vice president for Johns Mansville, instituted this policy with a company management decision. They would not hire people who were smokers in certain jobs and they tried, in parallel to what the railroad industry spokesmen said they are trying to do now, to limit that restriction to the jobs where there was residual exposure to asbestos.

The facts of asbestos are that your risk of lung cancer with asbestos exposure is about threefold to fivefold increased compared to the nonsmoking, non-asbestos-exposed population. If you're a smoker working the same area, your risk is about ninetyfold, substantially enhanced by the larger factor for the cigarette smoking, which is synergistic with the asbestos exposure.

Mr. GORE. But it's my understanding that was overruled.

Dr. OMENN. Congressman, as of the most recent conversation I had with Dr. Kotin about 2 years ago, they had had no court ruling. In three arbitration rulings they were upheld on the plan which was to deny new employment to smokers and to force smoking workers to make a choice between staying in this particular job or moving to a different job or staying in that job and accepting a program which would assist them to stop smoking. And at least at that time there was a consistent record that the environmental control efforts were satisfactory and that the education and objectives of the cigarette smoking policy were largely in the workers' interest.

Mr. GORE. You may be quite correct. We'll check it and cite it for the record.

Dr. OMENN. I'll check it too. I may see Dr. Kotin.

[The material follows:]

As of November 22, 1981, according to Dr. Kotin, there have been four arbitration rulings dealing with the Johns Mansville policy about smoking workers. The first three upheld the company policy against employing current smokers in certain jobs. The fourth (affecting their Texas plant) went against the policy. On appeal, the relevant court gave a modified ruling: the no-smoking policy was upheld with regard to smoking on the job at the particular sites, but the workers retained the right to smoke in certain areas away from the job sites on break time. Thus, at this plant, Johns Mansville cannot restrict smokers from certain jobs; at all other plants, they may still do so.

In terms of the six mechanisms of adverse effects of smoking in the workplace (See pages 128/129 of the testimony), this judicial compromise reduces the risks associated with at least three of the mechanisms (#2, 3, 6).

That really summarizes my remarks. I would say overall there's been relatively little progress and very little activity in industrial screening in the last 5 or 10 years. Perhaps your hearing will stimulate the development of the kinds of information required for intelligently advancing this work.

[The prepared statement of Dr. Omenn follows:]

STATEMENT ON SCREENING FOR HIGH RISK GROUPS IN THE WORKPLACE

Gilbert S. Omenn, M.D., Ph.D.

before the

Subcommittee on Investigations and Oversight

House Committee on Science & Technology

October 14, 1981

Mr. Chairman and Members of the Committee:

I am pleased to appear before the Committee today, as requested, to discuss the state-of-the-art of diagnostic screening tests, especially for genetic predispositions, and the need for rigorous technology assessment in the application of such medical approaches to the workplace.

There are three classes of reasons for screening tests, including pre-employment screening tests:

- 1) to protect the worker: many individuals may have pre-existing diseases, personal habits, specific disabilities, or genetic predispositions which make him or her much more likely than the average worker to develop illnesses or become injured on the job. Exclusion from the job is seldom the desired outcome of such findings; instead, counseling about risk factors, advice and training about work practice, or modification of the job requirements can overcome many of these factors. As a physician, I can assure you that a common question from ill workers is: "Doc, why did I get this? Lots of other guys work in the same conditions. Why me?" In order to give good and individualized medical attention and, even better, in order to anticipate and prevent such occurrences, there must be an organized effort to develop better understanding of significant predispositions and to devise and validate appropriate tests. I will return to this recommendation later.

2) to support the regulatory process: the Occupational Safety and Health Act (Section 6(b)(5)) orders "the Secretary, in promulgating standards..., (to) set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life" (emphasis added). It is difficult enough to establish a standard which will assure that no worker, no matter how predisposed by genetic traits or illness or personal habits, will suffer impairment of health or function, unless that standard is zero exposure. But it is truly a requirement for Solomonic wisdom to accomplish that objective while respecting all the factors embodied in the term feasibility. Such is the mandate in an Act of Congress!

It is clear from English common law and from many decades of labor/management tension in this country that primary responsibility for ensuring a safe workplace rests with the employer. OSHA usually takes the position that essentially all responsibility for a safe workplace rests with the employer, and many commentators--from Studs Terkel in his remarkable book Working to union leaders like Anthony Mazzochi--drive home the point that the conditions of work in many industries are such that it is unfair to lay any responsibility for self-protection upon the worker. Nevertheless, review of NIOSH criteria documents and OSHA general industry standards* reveals an elaborate array of required and recommended pre-placement and period¹ post-employment examinations and tests. For many, family history and "genetic factors" are mentioned specifically.

*OSHA Medical Surveillance Requirements and NIOSH Recommendations: For Employees Exposed to Toxic Substances and Other Work Hazards. Prepared by BioTechnology, Inc, for NASA Occupational Health Office, January 1980. Made available by NIOSH.

Unfortunately, neither NIOSH nor OSHA has supported any significant research into the detection of such predisposing factors or development of tests for metabolic and other differences known from general pharmacology. The situation is not much better with EPA. Section 109 of the Clean Air Act and the supporting legislative history require EPA to set ambient air quality standards so as to protect the most susceptible subgroups in the population and do so with an adequate margin of safety. EPA has made major efforts in the standard-setting process to identify high-risk groups in the population for effects of photochemical oxidants or ozone (those with asthma, bronchitis, and emphysema) and for effects of airborne lead (children). These groups are not very specific, and research data are very limited. EPA had to utilize data from studies not designed for such interpretation. If the Congress intends for EPA and OSHA to continue to try to set standards to protect the most susceptible or highly susceptible subgroups in the population, then research focussed on delineating such subgroups will be necessary.

3) to reduce the employer's liability: in addition to matching workers and jobs to ensure maximal productivity and job satisfaction, employers have an undeniable interest in providing a safe workplace and in motivating and/or selecting workers to have low injury and illness records. Pre-employment examinations may serve an important medicolegal purpose. Some states allow the use of pre-employment data in computing disability for workmen's compensation awards for occupational disease. (Of course, as is well known, recovery for illnesses under workmen's compensation is far more difficult than for injuries.) Notable among these cases is use of pre-placement audiograms. As Imbus pointed out (in *Occupational Medicine: Principles & Practice*, YearBook, 1975), this practice may be extended to pulmonary diseases. Many states have provisions for second injury and/or handicaps in their workmen's compensation laws that

allow the pre-existing component of an occupational disease to be deducted from either the employee's benefit or from the employer's premium. A special fund has been established in some states that allows the employee to be awarded the full amount for his disability, but the payments for the pre-existing component are taken from a general fund rather than directly from the employer's premium. Obviously, where such provisions exist, it is important for the employer to determine the health status of the employee at the time of employment.

Despite the reasons given above and despite continued costly screening procedures, pre-placement evaluation has fallen into considerable disrepute. Its benefit to either the employee or the employer has been challenged. In high-turnover, low-hazard industries there may be a poor benefit/cost ratio. Some industries have approached this problem by reducing costs through use of paramedical personnel, especially nurses, to do the evaluations, which is generally quite satisfactory. Another reason for the disrepute is the often poor quality or lack of specific relevance of the evaluation and tests to the particular hazards in a given workplace. A third reason is the disparity in interpretation by physicians or others: if overly liberal, individuals may be employed who cannot do the job, or--even worse, of course--who are injured or become ill (for example, individuals with heart disease in hot and stressful environments, or those with pre-existing symptomatic back conditions in heavy lifting jobs); on the other hand, overly rigid interpretation will lead to rejection of individuals who are perfectly capable of performing the job. The recognition that highly motivated individuals can often overcome seemingly serious physical handicaps is influential, as well.

Genetic Differences

There can be no doubt that people differ remarkably in many body functions and in the underlying genes and gene functions. Studies have been done for many years of individual variation in blood groups, plasma proteins, red blood cell enzymes, histocompatibility/antigens, and now DNA sequences. At all levels of investigation, very significant variation has been demonstrated. Such variation is the basis for evolution and adaptation of our species and surely accounts in part for the capacity of humans to live in so many varied physical circumstances on this planet. Screening just a tiny fraction (less than 1 percent) of the expected number of variant proteins we find that no two persons (except for identical twins) will be likely to have the same profile of results. Specifically, a battery of about two dozen blood groups, plasma proteins, blood cell enzymes, and the histocompatibility antigens gives a probability of about one in 4 billion that two unrelated people will have the same results. We geneticists, like the poets, enjoy pointing to the uniqueness of the individual!

Genetic Screening

Several kinds of genetic screening have been carried out. For our purposes today, the relevant kind of screening program is that directed at populations, rather than individual patients. Studies of patients who come seeking medical attention are carried out in a very different context from screening tests on unsuspecting and often inadequately-informed individuals in some group in the general population. The best known examples are newborn screening for phenylketonuria (PKU) and childhood or pre-marital screening for sickle-cell disease and sickle-cell trait and for Tay-Sachs disease. PKU screening is required by law in nearly every state and is credited with saving many children from lives in institutions for the mentally retarded. The development of a special diet

which overcomes the metabolic defect in these children and allows normal mental development is one of the wonderful results of modern medicine. However, even this screening program is not lacking for problems. First, the screening turned up twice as many cases as expected on the basis of the prevalence of PKU in the institutions for mentally retarded. Only later did physicians and researchers realize that the test was not enhancing case-finding for PKU, but was classifying as PKU children whose high blood phenylalanine levels (the basis for the test) were due to other reasons and generally harmless. In a few cases, administration of the special low-phenylalanine diet was not only not helpful, but also acted to impair brain development. Even with very high sensitivity and specificity of the test, given the low incidence of PKU (1 per 15,000 Caucasians; 1 per 100,000 Blacks) many false-positives and still a few false-negatives occur, as Holtzman of Johns Hopkins has emphasized.

Screening for sickle-cell disease and trait was bedeviled by confusion about the two conditions. The sickle-cell disease is a serious anemia of children, usually already diagnosed or diagnosable clinically before school age. It is due to a double dose of the abnormal hemoglobin gene. Sickle-cell trait is the carrier state in the parents and some (2/3) of the siblings of affected children and in about 8 percent of the American Black population. It is accounted for by one abnormal hemoglobin gene in the presence of one normal gene (one from each parent). It is generally associated with normal health. Unfortunately, some people confused the disease and the trait. Medical reports added to the confusion, as individual cases of persons with sickle cell trait and some infection or other problem were reported; in all likelihood these were coincidences, given that 8 per cent of Blacks have the trait. Population-based research, rather than individual cases, was essential in straightening out this situation.

Screening may be carried out for predisposing conditions that are totally asymptomatic, rather than for biochemical signs of serious illness. In addition to sickle-cell trait, many conditions are known which predispose individuals to adverse effects from drugs and other environmental agents (see Table). Since drugs are simply one class of environmental chemicals, we are long overdue to investigate whether the same persons are at higher risk for adverse effects from inhaled chemicals with similar properties. Exposures to such chemicals and irritants may be particularly high and be more easily related to specific chemicals in the workplace than in the general environment. Such logic has generated recommendations for more than 15 years of testable traits which might be suitable for screening in the workplace, but the necessary research to determine whether there really is an enhanced risk and to estimate the significance of that risk has yet to be performed.

Genetic Screening in the Workplace: What Might be Tested?

Tests that have been proposed are these:

1. Serum anti-trypsin deficiency and predisposition to chronic pulmonary disease: Pulmonary emphysema is characterized anatomically by destruction of the alveolar air spaces of the lung. The mechanism appears to be proteolytic enzyme damage by enzymes released from white blood cells and macrophages in the lung. Normally these enzymes are regulated and inactivated by circulating serum alpha-1-antitrypsin. About one person in 2000 (in Sweden) or one person in up to 10,000 (in some populations in the US) have a severe deficiency of this protein and are clearly predisposed to development of emphysema in early adult life, with the risk exacerbated by smoking. These individuals have a double-dose of the abnormal gene and its protein effects. Individuals who are carriers (single-dose of the abnormal gene) are much more frequent, constituting 2 to 4 percent of the population. There is some evidence that they are predisposed to emphysema also, especially if they are cigarette smokers, but the test is complicated by infections and other

TABLE 2
GENETIC VARIATION IN HUMAN SUSCEPTIBILITY TO
ENVIRONMENTAL AGENTS

EXAMPLES IN VARIOUS CLASSES OF AGENTS

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1. Drugs
 - a. Glucose-6-phosphate dehydrogenase (G6PD) deficiency and oxidant drugs: hemolytic anemia.
 - b. Methemoglobin reductase deficiency and oxidizing agents: hemolytic anemia (effects in heterozygotes).
 - c. Acetylation in the liver: side effects of many drugs.
 - d. Plasma pseudocholinesterase and sensitivity to suxamethonium.
 2. Inhaled Pollutants
 - a. Alpha-1 anti-trypsin deficiency and emphysema.
 - b. Induction of aryl hydrocarbon hydroxylase and lung cancer.
 - c. Metabolic conversion of nicotine and bladder cancer.
 3. Foods
 - a. Lactose intolerance: milk and diarrhea.
 - b. Wheats gluten and celiac disease (malabsorption).
 - c. Food high in saturated fats and predisposition to atherosclerosis.
 - d. Fava beans and hemolytic anemia (G6PD deficiency).
 - e. Goitrogens and thyroid disease.
 - f. Catecholamines in cheese and chocolates and migraine.
 4. Food additives and stimulants
 - a. Furfurylamine and other additives.
 - b. Iron supplements.
 - c. Caffeine.
 - d. Alcohol.
 5. Physical agents
 - a. Cold weather stress.
 - b. Motion sickness.
 - c. Ultraviolet radiation.
 - d. X-irradiation.
 - e. Metal poisoning.
 - f. Color vision.
 6. Infectious and Auto-Immune Disorders.
 - a. Predispositions associated with impaired antibody production or cellular immunity.
 - b. Predispositions associated with histocompatibility system.
-

From Omenn (1979)

variables and the enhanced risk, if any, must be small. It is interesting that knowledge of this genetic mechanism for predisposition to emphysema has stimulated studies of the effects of smoking; even brief cigarette smoking has been shown in humans, as well as rats, to significantly decrease the capacity to inhibit proteolytic enzyme action in the lung.

Only desultory screening for antitrypsin deficiency or carrier state has been carried out in industry. The low incidence, combined with uncertainty about the effects in the carriers, has led to abandonment of this test.

2. Glucose-6-phosphate dehydrogenase (G6PD) deficiency in red blood cells (and other tissues): This X-linked genetic abnormality predisposes affected males to hemolytic crisis (breakdown of red blood cells with resulting anemia) from a long list of oxidizing drugs, naphthalene, and fava beans. There are striking differences in gene frequency across populations, with distinct enzyme variants in Mediterranean and in Black populations. In both cases, the gene became frequent because it conferred an advantage in surviving childhood malaria. There is every reason to believe that such individuals (about one-third of males in these groups) may be predisposed not just to oxidizing chemicals administered as drugs, but also to oxidizing chemicals experienced as occupational chemicals or air pollutants. The only case reports have come from Israel, where a handful of G6PD-deficient Iraqi Jews developed acute and severe anemia while working in a TNT plant. Workers dealing with nitro-amino compounds and nitro-aromatic compounds should be investigated. Ethnic background of the workers is highly relevant. Screening of workers lacking Mediterranean or African ancestry will be unfruitful. It is clear that any such screening must be as a research project, not as a routine at this point.

3. Sickle-cell trait or disease: There is no basis for suspecting that such individuals are predisposed to chemicals. There is substantial basis for suspecting that even those with sickle-cell trait are predisposed to sickling if exposed to low oxygen tensions at high altitude without pressurization. On such basis, the Air Force for several years excluded Blacks with sickle-cell trait from pilot training. That practice was challenged, since there were no data to prove the extent of risk and since loss of pressurization is so infrequent that other performance factors were judged more important. Screening for sickle-cell trait in general industry has been carried out primarily, perhaps only, for purposes of supporting voluntary counseling programs for employees unrelated to the job exposures. Given the disputes about management's purposes, perhaps it is better to leave such screening to the community and to the individual.
4. Atypical Cholinesterases in plasma: One of the most dramatic pharmacogenetic disorders known occurs with a frequency of about 1 in 2000 Caucasians (much lower in Blacks) and is due to an atypical or abnormal form of plasma pseudocholinesterase, the enzyme which rapidly inactivates succinylcholine, a drug given to paralyze the muscles for anesthesia or for electroshock therapy. The atypical enzyme fails to inactivate the drug, leading to continued paralysis, including paralysis of respiration. If unsuspected, the death of the patient will be attributed to surgical or other unknown factors. If suspected, artificial respiration and plasma infusions can save the patient. A simple bedside screening test is available but, unfortunately, is seldom used. The plasma enzyme variation has nothing to do with susceptibility to organophosphorus and carbamate pesticides, which attack tissue cholinesterases, so testing this enzyme has no value in such exposures. However, a new enzyme has been described which deserves investigation (below).

5. Tests for skin sensitivity: organic isocyanates. Toluene diisocyanate (TID) is one of many isocyanates used in the manufacture of polyurethane foams. People differ in their susceptibility to hypersensitivity reactions to this (and other) chemicals. Some are extremely sensitive. Personal and family histories are indicated, but tests have not proved practical. This area of dermatologic occupational medicine clearly needs more work, since seven of every ten industrial disease claims paid by insurance companies are for industrial dermatitis.

New Tests Worthy of Investigation

Two metabolic polymorphisms have been described recently. Both deserve investigation in occupational settings.

1. Paraoxonase polymorphism. This plasma enzyme inactivates parathion and paraoxon and probably also malathion. About half of the population (Caucasians and Blacks) have a low-activity form of the enzyme, with only a third or a sixth of the activity of those with the high-activity form of the enzyme. The population genetics and biochemistry of the enzyme variation are being worked out. It is timely to test the significance of this metabolic variation in the susceptibility of spray pilots, applicators and mixers, and field hands exposed to these pesticides. In my own State of Washington, there have been some 167 claims paid by the State to covered workers for parathion poisonings.
2. Debrisoquine/sparteine oxidation: The drugs debrisoquine and sparteine and several other drugs metabolized by various carbon oxidation mechanisms in the liver microsomes show a striking difference across individuals: about 9 percent of Caucasians have essentially no oxidizing capacity for these drugs, while "normals" convert the vast majority of the drug to oxidized derivatives. The difference in activity may be as much as 20,000 fold. Although the mechanism

of action is just being investigated in detail, it is likely that cytochrome P450 structures or matrix are involved. These same enzyme complexes are critically involved in activation of many chemicals which are well-established carcinogens, mutagens, and teratogens. A single genetic locus in the mouse accounts for most of the variation in such activating functions. One study in Nigeria among patients with aflatoxin-induced cancers has already indicated that the debrisoquine poor metabolizers may be relatively protected from aflatoxin-induced cancers (failure to activate the aflatoxin). Aryl hydrocarbons in cigarette smoke and in air pollution are activated by a related system. It is not yet known whether the difference in enzyme activity is expressed also in a difference in activating the aryl hydrocarbons. If a useful test could be developed to subdivide smokers into those with very high risk of inducing carcinogens and into those with a less high risk of the same, there would be many applications in the general population and in the workplace.

Cigarette Smoking

It would be irresponsible to discuss "hypersusceptible workers" without focussing attention on the problem of cigarette smoking. The Surgeon General's 1979 Report on Smoking and Health, a NIOSH Bulletin (#31 in American Industrial Hygiene Association Journal, 1979), and many other reports emphasize the severe exacerbation by smoking of workplace hazards of several kinds. These include the following:

1. Certain toxic agents in the workplace also occur in tobacco products or smoke, increasing the exposures: carbon monoxide, cadmium, many others
2. Workplace chemicals may be transformed into more harmful agents by burning tobacco: polymer fume fever (temperature of burning tobacco in a cigarette is about 1600°F or 875°C)

3. Tobacco products may serve as vectors by becoming contaminated with toxic agents from the workplace, facilitating entry into the body by inhalation, ingestion, or skin absorption: tetrafluoroethylene polymer, lead, pesticides.
4. Effects of smoking may be additive with effects of agents in the workplace: chlorine, cotton dust, coal dust, beta radiation.
5. Smoking may act synergistically with effects of agents in the workplace: asbestos, gold mine exposures, rubber industry exposures, radon radiation products.
6. Smoking may contribute to accidents in the workplace: loss of attention, preoccupation of the hand, irritation of the eyes, cough, fires.

In delivering the 1979 Ernestine Henry Lecture at the Royal College of Physicians in London, Elmes analyzed the relative importance of cigarette smoking in occupational lung disease (British Journal of Industrial Medicine 38: 1, 1981). Both in the UK and in Germany there is substantial evidence that within the coal mining and the iron and steel industries conditions are now such that dust exposures contribute much less to morbidity or mortality than do workers' smoking habits. While control of occupational exposures to various respiratory hazards remains important, a far greater improvement in respiratory health would be produced by controlling tobacco smoking. In addition, of course, smoking has major deleterious consequences for the cardiovascular system. The genetic variation noted above in alpha-1 anti-trypsin levels and in the aryl hydrocarbon hydroxylating system probably will prove important in smoking effects on the lung, but may be unrelated to the mechanisms of smoking effects on the cardiovascular system.

Opportunities for Research

While it is clear from the discussion above that no genetic screening tests should be applied routinely at the present time, I have urged in several places that research be stimulated. It is reassuring to note that good relations among unions, management, and academic researchers can be achieved. A model is the

three-way arrangement of investigators at the Harvard School of Public Health the United Rubber, Cork, Linoleum and Plastic Workers of America (URW), and the B.F. Goodrich, Armstrong Rubber, and Mansfield Tire & Rubber companies. A formal agreement was signed in 1971. An Occupational Health Committee, composed of management and union representatives, reviews and approves the research plans, makes recommendations for implementation of the findings, and reviews occupational health problems identified by local health and safety committees for possible referral to the university. The Occupational Research Study Group at Harvard conducts epidemiologic studies and in-plant investigations and assists in the development of safe standards for occupational environments.

Another example of cooperative activity can be found at the University of Washington. The industrial hygiene program of the Department of Environmental Health is supported by the State Department of Labor and Industries, with an oversight committee that includes representatives of the State Labor Council and of companies.

I am persuaded that explicit arrangements can be made to permit research investigations and to specify the uses of data and access to data. It is essential that all participants recognize the differences between open-minded research and the potential subsequent application of tests, if validated, for routine screening and surveillance. The Harvard and University of Washington examples provide for workers' consent for studies of safety and health risks, although it is not clear how much involvement individual workers actually have or feel.

Concluding Remarks

In closing, I will touch upon the specific questions you raised, Mr. Chairman, in the letter of invitation.

In general, I believe that the extensive medical histories and physical and laboratory examinations carried out on workers and prospective workers too often lack a validated basis or adequate relevance to the particular exposures of the worker's environment. As you know, Rockey, Fantel, and I recently published a very critical analysis of the use of pre-employment back x-rays; Dr. Rockey is testifying before the Committee today, as are representatives of the railroad industry, where the x-ray screen is still widely utilized, despite its poor predictive value. There is a genetic twist on the screening for low-back problems. The histocompatibility antigen B-27 is strongly associated with one type of low back problem, called ankylosing spondylitis; some physicians have recommended doing this test, which involves no radiation exposure. Even though individuals with B-27 have a roughly 200 times higher risk of ankylosing spondylitis than do people without B-27, the absolute risk is still low (about 5 percent for symptoms that are clear-cut, perhaps up to 20 percent for suggestive symptoms). Not only would a positive B-27 test not be basis for excluding workers, but also this lab test would miss the rare patient with some remediable back condition!

With regard to specific genetic markers, we know a great deal about genetic variation for certain traits in the general population. Unfortunately, research into the consequences, if any, of such variation in the workplace settings is only beginning. We can suggest here the criteria which should guide the development of any research results into potential tests:

- o the prevalence of the predisposing trait must be sufficient to be detected in usual worker populations; usually this will mean at least 5 percent prevalence but "sufficient" will depend upon the reliability and cost of testing and the relative risk and its consequences

- o the prevalence in various subgroups in the population should be determined, since genetic traits often occur with differing prevalence in different ethnic or geographic groups

- o the relative risk for a significant adverse outcome must be at least 3 (risk for those with the trait compared with those lacking the trait), based upon experience with relative risks for histocompatibility types associated with various diseases; preferably the relative risk should exceed 10 times, so as to enhance the likelihood that the particular tested predisposition is, indeed, putting those workers at significantly higher risks than other presumed but non-testable predispositions within the overall population

- o the test itself must be reliable, inexpensive, and well-characterized for false-positives and false-negatives

- o there must be a clear understanding with management and workers about how test results are to be utilized, what actions might be based upon the results. /

There is no point in using unvalidated tests for screening purposes.

Also, there is no point in assessing genetic variants in situations with overall low risk. For example, the one remaining possible hazard for sickle-cell trait is exposure to low-oxygen environments in flight accidents or high-altitude military or mountaineering exercises. The Department of Defense as of January, 1981, finally recognized that there was no factual basis to continue excluding blacks with sickle-cell trait from the Air Force Academy or from pilot training; some had slipped through the screens anyway and preliminary follow-ups are benign. However, with the new policy of non-exclusion the military is launching careful surveillance studies to monitor and assess this question with data.

If and when properly developed and validated tests are available, the usual processes for determining standards and recommending tests should apply. NIOSH, as recently as a presentation yesterday to a National Academy Panel on Risk Assessment, has stressed its interest in identifying and protecting especially susceptible workers.

It is premature to speculate what should be done to the workplace or with the worker practices or both in response to a particular, yet to be discovered predisposing condition. Efficient, ethical, and effective responses will depend

the specific predisposition, the relative risk, the practicality of modifying the enhanced risk for the predisposed worker (and possibly for all other workers at the same time) by altering the environment, or altering work practices, or altering associated risk factors. The most important real-life test of how we might respond to a specific risk factor is the major contribution of cigarette smoking to so many occupational health problems. When we consider so-called "hypersusceptible" workers, the most compelling group of workers--and a large proportion--is the smoker. We should emphasize also the apparent adverse effects to co-workers who are not smokers both from the smoke and its contents and from the increased accident rates. The most desirable means of addressing the smoking problem, in my view, is through a vigorous health education campaign in which unions and management voluntarily participate and in which individual workers can be encouraged to take steps to enhance their own health.

Your question about screening serving as a substitute for improvements in workplace quality is central to the labor/management tension over responsibility for workplace safety. As Elmes has stressed, however, substantial improvements in work conditions in the coal, iron and steel, asbestos, and slate industries have had far less overall results than would be feasible if reduction of smoking had accompanied these environmental changes. It is my impression that the Johns Mansville Company policy to assist workers in certain jobs to stop smoking or switch jobs has been supported in arbitration rulings primarily because the company made very substantial investments in reducing exposures and did actually control most of the asbestos dust exposures. The genetic predispositions--if and when screening tests are developed--will serve to identify workers for whom the usual surveillance program may be an evaluation of the adequacy of environmental controls to protect highly susceptible workers. If adequate, such information should be reassuring also to less susceptible workers. As in the Johns Mansville smoking policy, however, there will come a point at which it may be infeasible technically or too costly by some criteria to offer environmental protection. Personal preventive health measures or job-switch would be required

Your final questions, still hypothetical, about whether workers should be permitted to assume risks, either health risks or liability risks, move into legal ground for which I have no background. I believe it would be difficult to prove that the worker seeking compensation had fully comprehended the "choice" made years earlier. In states with workmen's compensation programs that allocate responsibility there may be precedent for dividing the risks, but I doubt that we can find much precedent for informed consent for the kind of risk-taking you raise. In general, our society seems to tolerate an extraordinary degree of risk-taking by individuals, even when innocent others may be injured or be left parentless or when the costs of the consequences must be borne by the society. For so-called "involuntary risks", our social position has been that such risks should be eliminated entirely or reduced to as low levels as feasible. I recommend that some careful legal analysis and some detailed analysis of specific instructive potential cases be carried out in order to provide a sound response to your question.

There has been relatively little progress and almost no activity in industrial screening for genetic traits during the past 5 or 10 years. Perhaps your hearing today, Mr. Chairman, will stimulate the development of the kinds of information required for intelligently advancing this work.

Mr. GORE. Well, I appreciate your concluding comment. It's our hope that we will play a constructive role in trying to focus attention to these troublesome issues before they reach a stage where they will be almost impossible to solve.

Do you agree with the view of the future that I have expressed regarding the role of HLA antigen screening and other forms of genetic screening?

Dr. OMENN. In general I do, but I think it's going to be much more slowly coming than you expect. The HLA story burst upon us 8 or 9 years ago. From a scientific point of view we thought we finally had got a handle on these arthritic conditions, but it turns out, despite hundreds and hundreds of papers redocumenting the same association, we really don't know any more now than we did then about what it is that is the underlying mechanism for the ankylosing spondylitis or certain other conditions.

The particular tests, some of which I summarized here, have been spoken about for possible use in screening for 15 years. Every 5 years or so there's a summary of the field for the Joint Conference on Occupational Health. I happen to be giving that summary tomorrow in Nashville, but the fact is that from reading what was stated 10 years ago and 5 years ago and tomorrow, there's been no progression. In fact, what we are saying now may have some chance of finally moving the field forward. We ought to move away from the focus on screening per se and get some sound information upon which to make judgments that will be valid scientifically and draw the interest and cooperation of workers and management for selection of appropriate tests.

I think it will be very important, when organized screening is initiated to make good choices, to screen for risks important to the workers, not just for marginal hazard, and to insist on tests which are highly reliable and do not have too many false positives or false negatives.

Mr. GORE. In light of the earlier discussion submitted by the representatives of the railroad industry, it seems clear that the decision to use or not to use marginal markers will be substantially affected by the legal framework within which these decisions occur and while you say 300 percent is an appropriate cutoff point, the closest I could get with the earlier panel was somewhere around 3 percent as an appropriate cutoff point. Although no specific figure was given, that was an impression I was left with. That's quite a range of difference and where statutes like the FELA are concerned you're probably going to see tests that you would consider marginal.

Dr. OMENN. Well, I urge you and your staff especially to review the appendix material in the testimony of Dr. Meyers. I did not have it in advance and I don't have a copy, but I was glancing at it while I was listening to his testimony. If I heard and read him right, I understand his company's study of the past year to claim that the increased prevalence of back disability in what they describe as a high risk group compared to the low risk group was not 3, 5, or 10 percent; it was 2½-fold higher.

Mr. GORE. I understand that and I reviewed that appendix.

Dr. OMENN. And it even said six times higher. The basis of those numbers requires some considerable scrutiny. However, they are really in the same ballpark as I recommended.

Mr. GORE. Or think they are.

Dr. OMENN. Or think they are, exactly I suspect this concept of the marginal risk wasn't adequately appreciated in the discussion. The discussion was quite explicit, there's no doubt of that; but I think upon reflection they might like to reconsider the response.

Mr. GORE. Well, I hope so, but the considered response of the counsel present—not the medical director but the counsel—was that somewhere between 2 and 5 percent would begin to give the company some problems if they didn't do it.

Dr. OMENN. As you brought out, from a legal point of view, any risk—any risk which could be diminished by action the company might take—can be perceived to be in their interest and the interest of the particular worker that might be protected.

The problem is relating the potential benefit to the particular worker, to the population effect on many different workers and prospective workers. That's really the challenge.

Mr. GORE. And the problem is incurring liability if it's not done, which is where the pressure comes from.

Dr. OMENN. This is our general problem with defensive medicine. The Bureau of Radiological Health of the FDA has published in the last 2 months two documents which may be of interest to the committee with regard to this hearing. One is specifically on the low-back X-ray examination, in which they cite Dr. Rockey's work and work from the industry. The other is on the use of skull X-rays. As you know, anybody who's brought into the emergency room who has the slightest history of having his head in the vicinity of the accident, if an X-ray was not done, the hospital is defenseless against a later charge of missing neurological damage. Therefore there has been a tremendous increase in use of skull X-rays, despite a very poor predictive value. I refer those two documents to you: Your staff can obtain them.

Mr. GORE. OK. Well, thank you very much. It's been an interesting hearing, an interesting day, and we will go back into session tomorrow at 9 a.m. in this room.

I'd like to close with special thanks to the two participants who formed our last panel here and all the witnesses who have come today to help us out. Thank you.

[Whereupon, at 1:15 p.m., the hearing was adjourned.]

GENETIC SCREENING AND THE HANDLING OF HIGH-RISK GROUPS IN THE WORKPLACE

THURSDAY, OCTOBER 15, 1981

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT,
Washington, D.C.

The subcommittee met, pursuant to call, at 9 a.m., in room 1328, Longworth House Office Building, Hon. Albert Gore, Jr. (chairman of the subcommittee) presiding.

Mr. GORE. The subcommittee will come to order.

I would like to welcome our witnesses and others today. Yesterday we heard testimony on the economic incentives to conduct preemployment screening and the legal and ethical issues which invariably arise from such programs.

Such screening is designed to identify those portions of the work force which are at highest risk—those most susceptible to occupational disease.

The subcommittee heard testimony which questioned the capacity of many such screening programs to accurately identify a hypersusceptible segment of the population.

Among the points raised by the witnesses was the multi-factorial nature of occupational disease and the difficulty of selecting a single factor which could provide a meaningful basis for estimating an employee's vulnerability to illness.

The subcommittee also heard considerable testimony concerning the rights of job applicants and employees who are identified by such screening programs as belonging to a high-risk group.

There was considerable concern expressed that such screening could tend to supplant more expensive improvements in the quality of the workplace—that industry might attempt to modify the composition of the work force to fit existing environments rather than modify the environment so that it is safe for all employees.

Finally, we heard important testimony concerning new genetic screening techniques with which some industries in the recent past have experimented.

Although this technology is still in its infancy, it looms large on our horizon.

It is clear that we must consider industrial screening as one of the major potential human applications of our exponentially expanding knowledge of genetics.

Today, we turn to an extremely difficult example of workplace screening—the removal of fertile women from certain jobs which pose reproductive hazards.

In January 1978, the American Cyanamid Co., determined that all fertile women would be removed from exposure to certain toxic substances at its Willow Island, W. Va. facility.

The policy arose out of corporate concern that such toxins posed reproductive hazards and that exposed women would give birth to children with birth defects.

Because direct injury to the fetus can occur early in development when the mother might be unaware that she is pregnant, the company elected to exclude from such employment all women who could not show that they were incapable of bearing children. Five women subsequently underwent sterilization.

In January 1980, 13 women and their labor union brought an action against American Cyanamid under title VII of the Civil Rights Act of 1964, alleging sex discrimination.

This case illustrates yet another series of difficult problems which arise out of industrial genetic screening.

Sex is perhaps our most obvious genetic characteristic. It requires no sophistication to detect. We all literally wear our genetic markers.

Thus, we leave for the time being the issue upon which we focused yesterday—the availability of techniques to detect genetic sources of susceptibility and the accuracy of such methodology—and turn instead to industry's response to knowledge of genetic vulnerability.

Today, we will ask whether the removal of fertile women from the workplace effectively carries out the protective purposes upon which such removal was based.

Does it eliminate the potential reproductive hazards of the workplace? Are there other high-risk groups which the policy does not protect?

Specifically, are the fathers of children—the male members of the work force—also capable of transmitting the harmful effects of these toxins to the fetus later conceived?

Finally, are there any alternatives available to companies whose workers are exposed to reproductive hazards?

Before beginning, I would like to recognize the ranking minority member, Mr. Walker.

Mr. WALKER. Thank you, Mr. Chairman. I have no opening statement and look forward to hearing witnesses.

Mr. GORE. Our first witnesses will appear as a panel, Ms. Joan Bertin, from American Civil Liberties Union, Dr. Vilma Hunt, from Pennsylvania State University, and Dr. Jeanne Stellman of Columbia University.

We are delighted to have you here this morning. Without objection, the entire text of the fine written statements you provided will be placed in the record in full.

Mr. GORE. We invite you to present all or a summary of your statements at your own choosing and we will begin with Joan Bertin.

STATEMENTS OF JOAN E. BERTIN, AMERICAN CIVIL LIBERTIES UNION, VILMA HUNT, PENNSYLVANIA STATE UNIVERSITY, AND JEANNE STELLMAN, COLUMBIA UNIVERSITY

Ms. BERTIN. Thank you, Mr. Chairman. In the course of sitting in my office in New York City, I have heard a number of scary stories in the last couple of years, one of which you just recounted, that having to do with five women workers at American Cyanamid plant at Willow Island, who submitted to a sterilization operation in order to retain their employment.

Those women alleged they were threatened with termination of employment if they did not become sterilized.

I also heard of the following examples. A woman welder was denied entry to a worksite in Florida because she might be exposed to lead. She was not pregnant. She was not married, and she did not intend to have a child.

However, she was fired because there was no other employment for her.

Two women submitted to sterilization operations to keep jobs in which they were exposed to fluorocarbon 22. The employer had imposed this requirement on the basis of a study which was subsequently shown to be invalid.

Another woman was denied promotion to a job because her new job would expose her to vinylchloride, a known carcinogen to adults of both sexes. The reason for her exclusion was fear of injury to a fetus.

However, this woman was also single and had no intention of becoming pregnant.

A final example is a case of a woman widow with a grown son who applied for a job in which she would be exposed to coal tar. She was told she would not be hired because she was of childbearing capacity. She said, "I have no intention of having any more children. In fact, I am willing to submit to a tubal ligation in order to obtain this job. I have been unemployed for 6 months."

She was told if she got sterilized in order to get the job, she would not be hired.

Mr. GORE. Is that because the company was afraid then they might be accused of having required the sterilization?

Ms. BERTIN. I presume so. These case examples demonstrate the many varieties in which exclusionary policies have appeared. They have appeared around the country and they pose an agonizing dilemma for woman workers. That is, if you want to be employed or if you want to be promoted, you may have to become sterilized.

I talked to women who did, in fact, become sterilized in order to keep their jobs and I can tell you that the choice for them was, in fact, one of the most painful and terrible ones.

They made the choice only because they thought they could not provide for their families unless they did so and they felt that this responsibility superseded the responsibility they might have to themselves.

What we also know as a result of these stories that essentially filter in—we have no exact count of how many cases there are—is that many jobs are affected.

One commentator suspects it is 100,000 jobs. I think it must be considerably more than that because when we look at the indus-

tries involved, and when we look at the corporations which employ these policies, we know there must be far beyond 100,000 jobs involved.

I think this dilemma has to be viewed against some important facts. First of all, even on their own terms, these policies are grossly overbroad. The policies are geared toward protecting pregnant women or the fetus, but most women workers are not pregnant at any given point in time.

In fact, approximately 8.8 percent of the female labor force is pregnant on an annual basis.

I believe that that figure would be even lower in blue-collar occupations, which are the jobs we are primarily talking about, because in such occupations women tend to have their children earlier in life and then to go to work and to cease their childbearing after the age of approximately 35.

The second fact is the vast majority of births are planned and are wanted in this country. Census data says that among women with high school diplomas, only 9.8 percent of all births are unwanted.

As a third fact, we have to recognize that women workers bear heavy economic responsibilities for themselves and their families—60 percent of all women between the ages of 18 and 54 work.

That is to be compared with a figure of 88 percent for men. Those are 1979 figures. The Department of Labor estimated in 1978 that two-thirds of all women who work had sole responsibility for their own maintenance or that of their families, or that they supplemented family incomes of less than \$10,000.

Once again, there is a graphic illustration of this among the women who are actually subjected to these policies. Among the women at American Cyanamid who did become sterilized, they have reported and testified at depositions that prior to becoming employed at this chemical plant, they had worked for minimum wage. They had been employed as waitresses, stock clerks, grocery store checkout clerks, and similar kinds of jobs which paid, at best, minimum wage.

Many of these women went from subsidized income, meaning welfare level, to earning \$15,000 or more per year.

And one woman who had a high school diploma, said to me in a very poignant moment, "Who would have ever thought I could make \$15,000 a year?"

So, to the extent that exclusionary policies assume, one, that women's primary role between the years of 18 and 50 is childbearing or, two, that women workers do not or cannot control when and if they become pregnant or, three, that their employment interests are dispensable, these policies are based on reflective and stereotypical thinking that bears absolutely no relation to reality.

A second important fact is that these policies don't achieve their ostensible goals because they fail to take into account similar risks and similar liabilities to the future children of male workers.

I will defer to my scientific colleagues to amplify on this point, but I simply will summarize what my understanding of the science is.

There are many workplace conditions and substances which threaten genetic damage and other kinds of alterations in sperm

which can be carried to future generations of male workers in the form of birth defects and miscarriages and in the form of sterility or decreased fertility.

In fact, we know of more examples of men who have complained publicly that their work-place exposures have injured their children. I will give you a couple of examples that I think are well-known to everyone here.

The agent orange situation, of course, is well-known. The Vietnam veterans claim their exposure to agent orange has caused birth defects in their children and other ill health effects for themselves.

There are a number of men who work at a plant in Rensselaer, N.Y., who allege their exposure to the herbicide Oryzalin has resulted in birth defects in their subsequently born children.

That case is being investigated by EPA at the moment. The birth defects in that situation were of the most severe and heart-rending sort, having to do with serious heart defects and several deaths of young children.

Then there are two instances, DBCP and kepone, where the effects were male sterility or decreased fertility. It is interesting to note in both of those instances, once the correlation was established, the substance was banned; the worker was not excluded from the place of employment.

Research which has traditionally been directed exclusively at the female role in reproduction is now confirming what those stories suggest; that equal attention must be paid to the male population and that equal harm from male exposure to toxic substances is possible.

A final significant background fact is the pattern of implementation of exclusionary policies. These policies have appeared and occurred almost exclusively in industries which have been recently integrated by sex—sometimes, I must add, grudgingly so—and in jobs commonly referred to as nontraditional jobs for women.

It is peculiar that even where the same substances or conditions appear in so-called female-intensive industries that rely heavily on women workers, there has not been the same drive to "protect" them out of their employment.

For example, radiation. Health care workers are 75 percent women and they are exposed to radiation and a variety of other hazards, yet there is not a similar drive to exclude women from working as laboratory technicians, as X-ray technicians and the like. But women are almost never hired in nuclear powerplants.

Women in the textile and apparel industry and women laboratorians and others are exposed to various substances such as toluene and benzene.

When they are exposed to those substances in industries that rely heavily on women for employees, they are not excluded. However, when they are exposed to the same substances in chemical plants which have been recently integrated by women, they have been excluded.

This rule is not absolute, but there is a compelling pattern that appears. The pattern suggests a protective paternalistic response which may derive from intentional discrimination to keep women out of traditional male domains or which may derive from stereo-

types and untested assumptions about the proper place of women and their proper role in life.

Of course, we have to understand that exclusionary policies are proposed as an alternative to reducing toxic exposures to safe levels. Once again, here we run into another anomaly.

Industrial groups say they don't know what is a safe level for the fetus so they have to assume there is no safe level.

In other words, there is a zero-risk standard applied to fetal hazards, but where the risk is to the children of male workers or where the risk is to adults of both sexes, a different standard applies. Frequently, industrial groups will claim that there is no conclusive evidence to establish a causal relationship, so there is no need to be concerned.

An example of this is reported in the Department of Labor publication, "Protecting People at Work," indicating that in 1973, the Manufacturing Chemists Association has evidence of a correlation between vinyl chloride exposure and a rare and fatal form of liver cancer called angiosarcoma, but it kept that evidence a secret, even from Federal officials, so as to minimize unwarranted speculation.

The same point is demonstrated in comments submitted on proposed OSHA standards. Industry inevitably under estimates virtually every hazard, other than the fetal hazards, and consistently opposes the application of more rigorous health standards with regard to adult workers of both sexes and with regard to the potential hazard for male reproductive harm.

But where female exposure is concerned, they claim OSHA is not doing enough. Commonly there is no real evidence to support that claim, either.

In other words, they are way out ahead of OSHA in protecting the fetus from the hazards of maternal exposure, but they are dragged kicking and screaming into protecting everyone else.

I submit legitimate health policies would not display these inconsistencies, and exclusionary policies cannot be viewed as legitimate health policies for that reason.

That brings us to the question of what other explanation may be offered. It is no secret that the explanation is fear of future liability. However, that explanation does not quite make sense either, because there is the same potential for future liability to the children of male workers.

There are more known instances of adverse affects from paternal exposure than from maternal exposure. Then, there is the same potential for future liability to the community or to consumers, and I probably need only refer to Love Canal and Three-Mile Island. There was a lawsuit brought against the Bunker Hill Smelter for exposure of children in the surrounding area to lead.

Finally, let me make an analogy to the use of prescription and over-the-counter drugs. Drugs—like employment—have both risks and benefits. The drug companies make full disclosure of known risks and risks or dangers which have not been fully investigated.

It thereupon falls to the individuals involved to weigh the therapeutic value and benefit against the risks. That is a concept that it is very important to keep in mind in trying to formulate a proper resolution here. Drug companies bear the same potential liability

as chemical companies with regard to these potential hazards, yet the response has been quite different in the drug industry.

There is something wrong with the concept that you can solve the problem of potential liability by violating two Federal laws. The first, of course, is the Occupational Safety and Health Act, which requires employers to maintain a work place free from recognized hazards likely to cause serious physical harm, including fetal hazards, and the second is title VII of the Civil Rights Act of 1964 which prohibits discrimination on the basis of sex.

To conclude that an employer can protect itself against potential future liability by violating two Federal statutes, or even one for that matter, suggests two wrongs make a right. As a policy matter, that can't be.

As a final and concluding matter, these policies are not necessary because alternatives are available. It is possible to reduce or eliminate many of the risks we are talking about. There may be some cost attached to it, but cost is something which will eventually be integrated into the product produced. Society should be aware of the true cost of producing a product so it can make a determination as to whether or not it is worth it.

When I refer to reducing or eliminating risk, I am thinking of not only engineering controls, but of rotating jobs, plans of personal protective devices, voluntary transfer provisions and the like.

Where there is an inevitable risk that cannot be eliminated, the employer must inform the employees and provide voluntary counseling, monitoring and testing programs and provide temporary transfers to both men and women while they are planning pregnancies.

As a policy matter, we must allow individual employees to make these kinds of choices for themselves and to make their own assessment for risks and benefits with regard to employment.

Here let me point out a fact that few people recognize. That is, if a woman is fired during her pregnancy, she may become malnourished, and malnutrition is something very dangerous for fetal development.

So it is for the woman or the man to decide whether or not alternative employment is available or whether the duty to the present children requires that he or she remain in a particular job, even though it may pose some sort of risk.

If we don't accept this proposition, there is a danger that all kinds of immutable characteristics relating to race and national origin having to do with genetic characteristics could become the basis on which people are permitted to work in one job or another. For example, maybe type A personalities should not have high-pressure jobs, because they are prone to heart attacks under stress. Maybe fair-skinned people should not be permitted to work outdoors.

This kind of risk/benefit assessment is not at all unusual. People engage in it every day of the week and we all accept it. For example, if you drive your children to school in an automobile, you are engaging in a risky business. If you are over 40 and you elect to have a child, you are running the risk that your child may have Down's syndrome. That is also connected with paternal factors, as well as maternal factors. If you come from a population group

which has genetic predisposition to Tay Sachs disease, your child may also have that predisposition. Women who are pregnant drink alcoholic beverages, they smoke cigarettes, and drink coffee. All of those things present some risks.

However, life, unfortunately, is not entirely risk free and the individual is in a position to maximize benefits and to minimize risks. That is not a position which is shared necessarily, or under almost any circumstance I can imagine, by the employer.

Thank you.

[The prepared statement of Ms. Bertin follows:]

TESTIMONY

Of

JOAN E. BERTIN, ESQ.
Women's Rights Project
American Civil Liberties Union Foundation

BEFORE

Committee On Science And Technology
U.S. House Of Representatives
Subcommittee On Investigations And Oversight

October 15, 1981

Good Morning. My name is Joan E. Bertin. I am an attorney with the Women's Rights Project of the American Civil Liberties Union Foundation. I am grateful for the Subcommittee's invitation to address you on a matter of significant public importance - the legal and scientific validity of employment policies and practices which exclude women of child-bearing capacity from certain employment opportunities because of a professed concern for the safety of future generations.

These employment policies are widespread and threaten to deprive hundreds of thousands of workers - both male and female - of their civil rights; at the same time they fail to address the real problem of reproductive hazards in the workplace. Such policies are particularly invidious because they distinguish among workers on the basis of an inherent sex-based characteristic - the capacity to bear children - which women possess for most of their working lives. The rationale which underlies these policies, if accepted, could be extended to rationalize exclusions on the basis of race and national origin as well. For all these reasons the ACLU Women's Rights Project has undertaken a major, long-range effort to oppose the use of exclusionary employment practices and to encourage industry and government to adopt

other available lawful methods to address legitimate workplace safety and health concerns.^{1/}

It has been estimated that at least 100,000 jobs are closed to women because of exclusionary practices.^{2/} However, this would seem to be an extremely low estimate given the fact that approximately 835,000 persons are employed in lead industries alone,^{3/} and these industries commonly employ exclusionary practices. While I am unaware of any systematic survey to determine the number of companies having exclusionary employment policies directed at women, through firsthand knowledge, and reports in professional journals and the popular press, the following are some of the companies that have been identified as using these policies in varying forms: American Cyanamid, General Motors, B.F. Goodrich, Gulf Oil Corp., Sun Oil, Amax, Bunker Hill Smelter.

^{1/} We have undertaken extensive research and study on the question of the scientific and legal validity of exclusionary employment practices. Our efforts have also taken the form of direct litigation: we represent, among others, the women who challenge the American Cyanamid Company's exclusionary employment policy; we have appeared as *amicus curiae* in such cases; for example, the challenge to the Olin Corporation's exclusionary policy under review in the United States Court of Appeals for the Fourth Circuit; we engage in public speaking and education to increase the information available to workers, health professionals, lawyers, and others about the scientific and legal aspects of this issue; and we have done administrative advocacy designed to assist federal and state regulators to accommodate the various competing interests and concerns raised by this issue.

^{2/} Williams, Wendy W., "Firing the Woman to Protect the Fetus: The Reconciliation of Fetal Protection with Employment Opportunity Goals Under Title VII," 69 Geo. L.J. 641,647 (1981) (hereinafter "Williams").

^{3/} The Lead Industries Association recommended the use of such practices in 1974. *Id.*

You may wonder why jobs with these companies are important for women. The answer is simple economics, and the implications extend far beyond the finances of a few women workers in each location. Most of the jobs involved require no skills or education and pay union-scale wages. One current collective bargaining agreement with which I am familiar provides for a starting hourly rate of approximately \$7.25, which excludes shift differentials, incentive pay and other bonuses. In contrast, unskilled women workers at best can ordinarily obtain employment only as waitresses, grocery store check-out clerks, household workers, or stock clerks - all jobs which at most pay the minimum wage. One client told me that her income tripled when she got a job in a chemical company, and that the difference in salary enabled her to support her family instead of relying on supplementary government assistance as she had previously been forced to do even though she worked full-time. She and other women report that these jobs had always been "for men only" until the federal government required revisions in the company's employment practices.

This pattern appears consistently: exclusionary policies occur in industries and occupations which have been historically closed to women. They are almost never seen in female intensive industries, even where the work-

place health and safety issues are similar.^{4/}

Women earn approximately 59¢ for every dollar^{5/} earned by men; a woman with a high school diploma on the average earns less than a man with an 8th grade education.^{6/} The wage gap is surely attributable to many factors. One of those factors is womens' inability to obtain certain kinds of lucrative employment because of employer's assumptions that it is not "suitable" work for a woman. My experience representing women who want to work in steel mills, in chemical plants, in the trucking industry, on construction sites, and the like, convince me that many women actively seek such employment, and that many more would actively seek it if they thought they might be hired. Even more women would want these jobs if they were informed of their high wage scales.

^{4/}See Williams, *supra* note 2, at 649.

^{5/}Perspective on Working Women: A Databook, U.S. Dept. of Labor, Bureau of Labor Statistics, Oct. 1980, Bulletin 2080, Table 52, "Median Annual Earnings of Year-Round Full-time Workers 14 Years and Over by Sex, 1955-78."

^{6/}The Earning Gap Between Women and Men, U.S. Dept. of Labor, Office of the Secretary, Women's Bureau, 1979, Table 8, "Comparison of Median Income of Year-Round Full-Time Workers, by Educational Attainment and Sex, 1977 (Persons 25 years of age and over)."

Exclusionary policies take various forms. Some policies restrict employment of women to those who can present medical evidence of sterility, making sterility a condition of employment for women. Other companies hire no women at certain locations, presumably to avoid the implication that they encourage sterilization to qualify for employment. One company refused to hire a fertile woman because she was fertile but told her they would not consider her application if she voluntarily obtained a tubal ligation. Some employers restrict certain jobs or locations, others restrict whole departments or lines of progression. All of these policies are designed to "protect" women from employment which allegedly may pose some hazard to a potential fetus.

51% of all women, and 50% of married women over the age of 16 work.^{7/} They do so out of economic necessity.^{8/} 64% of individuals below the poverty level are women.

^{7/} Marital and Family Characteristics of the Labor Force, March 1979, Special Labor Force Report 237, U.S. Dept. of Labor, Bureau of Labor Statistics, Jan. 1981, Table 4, "Labor Force Status of Women 16 Years and Over, by Marital Status, and Presence and Age of Youngest Child, March, 1979."

^{8/} Perspectives on Working Women: A Databook, U.S. Dept. of Labor, Bureau of Labor Statistics, Oct. 1980, Bulletin 2080, Table 64, "Poverty Status in 1978 of Women and Men by Age and Years of School Completed, March 1979."

Women head 84% of all single parent households.^{9/} While the poverty rate for all families is only 5.5%, it is 41.8% for single parent families headed by women with children under 18.^{10/} Thus, women, like men, work out of economic necessity to support their families; exclusionary policies directly limit their opportunities in this regard.

However, even if these policies had no such economic, social and political implications, they would still be objectionable. Exclusionary policies embody "stereotypes about the 'proper place' of women and their need for special protection." Orr v. Orr, 440 U.S. 268,283 (1979).^{11/} They

9 /Marital and Family Characteristics of the Labor Force, supra note , Table 1, "Number of Earners in Previous Year, by Type of Family in March 1970 and March 1979 and by Race, March 1979."

10/A Statistical Portrait of Women in the U.S.: 1978, Current Population Reports, Special Studies, Series P. 23, No. 100, U.S. Dept. of Commerce, Bureau of the Census, Table 9-10, "Poverty Status of Families, by Sex of Householder and Presence of Family Members Under 18 Years Old: 1977, 1975, and 1970."

11/Historically women have been subjected to restrictions on their employment originating from a professed concern for their health and the health of their offspring:

[H]er physical structure and a proper discharge of her maternal functions - having in view not merely her own health, but the well-being of the race - justify legislation to protect her. . . . The limitations . . . upon her contractual powers, upon her right to agree with her employer as to the time she shall labor, are not imposed solely for her benefit, but also largely for the benefit of all . . .

Muller v. Oregon, 208 U.S. 412,422 (1980). It is now recognized that state "protective" legislation denies women equal employment opportunities in violation of Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e, et seq., as amended ("Title VII"). E.g. Rosenfeld v. Southern Pacific Co., 444 F.2d 1219, 1225-26 (9th Cir. 1971).

are based on stereotypic and outmoded notions concerning women, viz., that women are always potentially pregnant and thus must be treated as if they are always actually pregnant, that women are unable to prevent pregnancy, that women alone are responsible for the health of their offspring, and that harm to future children can only occur through maternal exposure.^{12/} This is, of course, exactly what Title VII was intended to prevent - the denial of jobs to a particular person because of stereotypical assumptions concerning that person's sex.

Nor are these assumptions valid. Although most exclusionary policies apply to almost all female workers for virtually their entire work life,^{13/} statistics reveal that only a small number of women workers will have children after age 34.^{14/} In 1977, only one percent of married blue collar

^{12/}See pp. 10-15, *infra*.

^{13/}71.5% of all adult female workers in this country are under age 45, and 87.5% are under age 55. U.S. Bureau of Labor Statistics, Dept. of Labor, *Employment and Earnings*, January 1981. The effect of such a policy is thus for all practical purposes to exclude almost all women from the jobs in question, unless they are willing to submit to surgical sterilization.

^{14/}Of all women aged 55-59 in the workforce in 1978, almost 70% had had their last child by age 34; more than 90% had had their last child by age 39. U.S. Bureau of the Census, Dept. of Commerce, *Population Characteristics* 6, Table 15 (1979).

working women aged 30 or over expected to bear a child within the next year.^{15/} According to a survey prepared by the Department of Health, Education and Welfare in 1977, women workers who were pregnant during a one year period" . . . comprised about 8.8% of the estimated . . . [population of] ever-married women of reproductive age in the labor force at the time."^{16/} In the population of women aged 15-44 who have completed four years of high school, only 9.8% of all births were unwanted.^{17/} These facts indicate that the vast majority of working women are not pregnant at any given point in time, and that most women plan their pregnancies.

Thus, working women are generally in a very good position to know when and if they will have further pregnancies. It is reasonable to assume that women who have been fully informed concerning the possible effects of a toxic substance

^{15/}U.S. Bureau of the Census, Dept. of Commerce, Current Population Reports, Series P-20, No. 325, "Fertility of American Women: June 1977," Table B, at 3 (1978).

^{16/}National Center for Health Statistics, Advance Data From Vital & Health Statistics No. 11 (Sept. 15, 1977).

^{17/}U.S. Bureau of the Census, Dept. of Commerce, Statistical Abstract of the United States 67, Table 95 (1979).

on the fetus will take precautions to insure either that they do not become pregnant or that they will predict and detect pregnancy at an early stage.^{18/}

Secondly, and critical to the question of fetal safety is the fact that the health of a future child can be affected through both the male and female parent and that the only effective way to ensure fetal protection is to adopt a neutral policy which would protect both parents from damaging workplace exposures. A striking example of this proposition involves lead exposure, to which many exclusionary policies are directed.

The Occupational Safety & Health Administration's (OSHA) Lead Standard^{19/} rejected the absolute exclusion of

^{18/}Pregnancy can now be detected through a blood test 8 to 10 days after conception. J. Greenhill and E. Friedman, Biological Principles and Practice of Obstetrics 57 (1974). It is not necessarily true that a fetus is most vulnerable to damage from toxic exposure early in pregnancy, when a woman might arguably not be aware of her pregnancy. OSHA has found that where lead exposure is concerned "the first trimester has not been shown to be the period of highest vulnerability for the fetus." 43 Fed. Reg. 52,959 (1978).

^{19/}The Lead Standard appears at 43 Fed. Reg. 53,007-14 (1978), with minor amendments at 44 Fed. Reg. 5446 (1979), and at 29 C.F.R. § 1910.1025 (1979). The Preamble to the Standard appears at 43 Fed. Reg. 52,952-53,007 (1978), with Attachments at 43 Fed. Reg. 54,354-54,509 (1978).

fertile women, 43 Fed. Reg. at 52,960, and formulated instead requirements which apply equally to men and women workers who plan to parent children -- and approach which not only more effectively protects fetal safety^{20/} but which is also consistent with the terms and spirit of Title VII. In developing the Lead Standard, OSHA conducted more than eleven weeks of public hearings during which expert witnesses from around the world testified, 43 Fed. Reg. at 52,953; these hearings included "considerable testimony on reproductive effects," *id.* at 52,960. OSHA's conclusions with respect to the issue of fetal safety were as follows, *id.* at 52,959-60:

Germ cells can be affected by lead which may cause genetic damage in the egg or sperm cells before conception and which can be passed on to the developing fetus. The record indicates that genetic damage from lead occurs prior to conception in either father or mother. The result of genetic damage could be failure to implant, miscarriage, stillbirth, or birth defects. Based on the entire record, OSHA has reached the following conclusions regarding the reproductive effects of lead exposure:

20/See, 43 Fed. Reg. 54,389, 54,393 (1978). Toxic substances can affect the normal development of the fetus at three stages of the reproductive process. Gametotoxins are substances which cause malformations of the egg or sperm prior to conception thereby impairing the exposed individual's ability to conceive a healthy fetus. Mutagens are chemicals that cause alterations in the chromosomal structure of the DNA molecule in the male and female reproductive cells which can be manifested by abnormal fetal development (including birth defects) and genetic defects in later generations. Teratogens are substances which operate directly on the fetus and impair normal growth after conception. Stellman, The Effects of Toxic Agents on Reproduction, Occ. Health & Safety 36,36 (April 1979); Strobino, Kiene & Stein, Chemical & Physical Exposures of Parents: Effects on Human Reproduction and Offspring, Early Human Dev. 371,378 (Jan. 4, 1978).

- A. Lead has profoundly adverse effects on the reproductive ability of male and female workers in the lead industry.
- B. Lead exerts its effects prior to conception through genetic damage (germ cell alteration), effects on menstrual, and ovarian cycles and decreased fertility in women, decreased libido and decreased fertility in men through altered spermatogenesis.
- C. During pregnancy, the result of lead exposure may include spontaneous abortion, stillbirth, and damage to the fetus.
- D. Following birth the child of lead exposed parents may exhibit birth defects, neurological damage and the chances of death within the first year may be increased.
- E. To protect against the adverse effects of lead exposure to persons planning pregnancies (or pregnant) the blood lead level should be maintained below 30 ug/100 g. Although there is no evidence for a "no effect" level, OSHA believe the risk of reproductive effects would be minimized at this level. ²¹

²¹ /The Standard establishes the minimum for compliance with the Occupational Safety and Health Act. It does not require an employer to remove men and women workers planning to become parents who have blood lead levels over 30 ug/100 g; nor does it prohibit the removal of others. It does give such employees the right to insist upon temporary transfers to other jobs and to retain both their wage rates and their seniority during the period of such transfers. 43 Fed. Reg. 53,011-12 (1978). The legality of these provisions has been upheld. *United Steel-Workers of America v. Marshall*, 877 F.2d 1189, 1228-34 (D.C. Cir. 1980) cert. denied sub nom. *Lead Industries Assn., Inc. v. Donovan*, ___ U.S. ___, 49 U.S.L.W. 3964 (June 29, 1981).

In contrast, exclusionary policies assume that only women face reproductive hazards from lead exposure and that the only danger to the fetus occurs in utero. However, with regard to lead, this conclusion is amply refuted by the voluminous public record and findings compiled by OSHA.

Other exposures from which women have been excluded likewise pose risks to male reproduction and/or the health of adult workers of both sex. For example, spermatogonia are particularly sensitive to genetic damage from low-level ionizing radiation.^{22/} Carbon disulfide may pose a danger to the health of future children of male workers.^{23/} Vinyl chloride exposure has been correlated with a rare and fatal form of liver cancer,

^{22/}See, Report of United Nations Scientific Committee on The Effects of Atomic Radiation, at pp. 9,473.

^{23/}See, e.g., the President's Council on Environmental Quality, Chemical Hazards to Human Reproduction, § IV at 20-21 and pp. A at 11 (1981); NIOSH, Center for Disease Control, U.S. Dept. of Health, Education & Welfare, Guidelines on Pregnancy and Work 26 (1977) citing NIOSH, Center for Disease Control, U.S. Dept. of Health, Education & Welfare, Occupational Exposure to Carbon Disulfide, Rep. No. 77-136 (1977); A. Hricko with M. Brunt, Working for Your Life: A Woman's Guide to Job Health Hazards § C at 40-41 (1976); Stellman, "The Effects of Toxic Agents on Reproduction," Occupational Health and Safety 36,38 (April 1979). These and other sources suggest that toxic chemicals are rarely sex-specific in their reproductive effects. Williams, supra, n. 2, at 563-65.

a fact which industrial groups concealed "in order to minimize unwarranted speculation."^{24/} It may also cause genetic damage to sperm cells.^{25/} The insecticide lindane also presents a risk of cancer of the liver.^{26/} Dibromochloropropane ("DBCP") and Kepone cause male sterility, among other adverse health effects.^{27/} These risks are no less severe than the risks to which exclusionary policies are addressed, yet some companies have chosen to ignore these provable, known risks to living persons and to protect only against wholly speculative risks to potential future lives. A "zero risk" standard, while admirable in the abstract, cannot be so selectively and irrationally imposed.

Other factors suggest that vulnerability to reproductive injury through male exposure may be increased by social and biological factors. Women, particularly those in blue-collar occupations, tend to bear children before they begin to work, early in their working lifetimes. Men, on the

^{24/}U.S. Dept. of Labor, Protecting People At Work: A Reader In Occupational Safety and Health, 273 (1980).

^{25/}Ibid., at 275.

^{26/}U.S. Environmental Protection Agency, Lindane: Position Document No. 2/3, at p. II-6 (1980).

^{27/}U.S. Dept. of Labor, Protecting People at Work: A Reader in Occupational Safety and Health, supra note 24, at 296,306.

other hand, more often have children after they have worked for a significant period of time and have children over a longer time span. As a result, the years of workplace exposure per childbirth for men is significantly higher than for women.^{28/} Where a dose-response relationship exists or where an adverse affect may result from cumulative exposure, the children of male workers may thus be at greater risk.

Thus, men are equally vulnerable to reproductive hazards from toxic workplace exposures and are entitled to equal information about their susceptibility and equal protection from injury. That male workers now demand such protection can be seen from the complaints of Viet Nam veterans that their exposure to Agent Orange has caused birth defects in their children;^{29/} from male workers' claims

^{28/}This concept was developed by Vilma R. Hunt, Associate Professor of Environmental Health at Pennsylvania State University, formerly Deputy Assistant Administrator of the Office of Health Research, Environmental Protection Agency. Prof. Hunt is in the process of publishing a study containing supporting data.

^{29/}See, e.g. "Five Makers of Agent Orange Charge U.S. Misused Chemical in Viet Nam: Companies Replying to Suit Say Federal Negligence Is Responsible for Any Harm to Veterans and Kin;" N.Y. Times, Jan. 7, 1980, § A, p. 14, col. 1.

that their exposure to the herbicide oryzalin has caused birth defects in their children;^{30/} and from the complaints of male workers at the Olin Corporation's Brandenburg, Kentucky, plant.^{31/} These are but a few examples, but they demonstrate increasing concern of male workers that their jobs are hazardous to their children's health or that their jobs threaten their ability to have children.

Against this background, the logical fallacies inherent exclusionary policies are apparent. The policies also violate federal law, most clearly the right to equal

³⁰ /See, "Union, Citing Birth Defects, Asks Ban On A Herbicide," N.Y. Times, Nov. 9, 1979, p. 16, col. 1.

³¹ /The National Institute for Occupational Safety & Health (NIOSH) recently undertook a study in response to the complaints of male workers at an Olin facility in Brandenburg, Kentucky, that chemical exposures had adversely affected their reproductive capabilities, allegedly causing infertility and miscarriages in the wives of exposed workers. NIOSH findings, although preliminary, "strongly suggest a problem of toxicity to the male reproductive system affecting workers exposed" to the specific chemicals involved. NIOSH, Center for Disease Control, U.S. Dept. of Health and Human Services, Health Hazard Evaluation Determination Report, HE 79-113-728, Olin Chemical Company, Brandenburg, Kentucky 12 (1980), reported in 30 Morbidity & Mortality Weekly Report No. 17,205 (1981).

37/

employment rights guaranteed by Title VII.

The Legal Standard

Any exclusionary policy which overtly treats all women or pregnant women differently because of their presumptive child-bearing capacity constitutes a prima facie violation of Title VII. Title VII makes it unlawful for an employer "to fail or refuse to hire or to discharge any individual or otherwise to discriminate against any individual with respect to his compensation, terms, conditions or privileges of employment, because of such individual's . . . sex," 42 U.S.C. § 2000e-2(a)(1), and "to limit, segregate or classify his

37/Exclusionary policies may also violate the Occupational Safety & Health Act. The OSH Act promises "every working man and woman in the Nation safe and healthful working conditions." 29 U.S.C. § 651(b) (emphasis added). The District of Columbia Court of Appeals has indicated that exclusion of fertile women because of their allegedly greater vulnerability violates the Act: ". . . fertile women can find statutory protection from such discrimination in the OSH Act's own requirement that OSHA standards ensure that 'no employee will suffer material impairment of health . . .'" 29 U.S.C. § 655(b)(5) (1976) (emphasis added). United Steelworkers of America, v. Marshall, 647 F.2d 1189, 1238, n. 74, cert. denied sub nom. Lead Industries Assn., Inc. v. Donovan, ___ U.S. ___, 49 U.S.L.W.3964. The Court made it equally clear that OSHA has the authority and duty to protect against reproductive harm: "We find OSHA's contention that it has statutory authority to protect the fetuses of lead-exposed working mothers unassailable. Harm to fetuses, as OSHA contends, is a material impairment of the reproductive systems of the parents." *Id.* at 1256-57, n. 96. However, the Occupational Safety and Health Review Commission has rejected this logic and held that the use of an exclusionary policy does not violate the "general duty clause" of the OSH Act. Marshall v. American Cyanamid Co., OSHRC Docket No. 79-5762 (Apr. 27, 1981). That decision is presently on appeal.

employees . . . in any way which would tend to deprive any individual of employment opportunities or otherwise adversely affect his status as an employee, because of such individual's . . . sex." 42 U.S.C. § 2000e-2(a)(2). The exclusionary policy clearly denies women as a class equal terms and conditions of employment; it denies them employment opportunities; and it adversely affects their status as employees.

33 /

Title VII has been amended to insure that discrimination on the basis of sex "includes[s], but [is] not limited to, [discrimination] because of, or on the basis of pregnancy, childbirth or related medical condition . . . " 42 U.S.C. § 2000e(k). The amendment makes it clear that a classification based on the capacity to become pregnant is a classification based on sex. This intent is apparent from the legislative debates preceding the enactment of the bill. The House Report states that "[i]n using the broad phrase 'women affected by pregnancy, childbirth, and related medical conditions,' the bill makes clear that its protection extends to the whole range of matters concerning the child-bearing process." H.R. Rep. No. 95-948, 95th Cong., 2d Sess., 5, reprinted in [1978] U.S. Code Cong. & Ad. News 4749, 4753. Later, the House Report reiterates, *id.* at 7, [1978] U.S. Code Cong. & Ad. News at 4754-55:

33 / Pub. L. No. 95-555, § 1, 92 Stat. 2076, 42 U.S.C. § 2000e (k). This amendment became effective on Oct. 31, 1978.

Women are still subject to the stereotype that all women are marginal workers. Until a woman passes the child-bearing age, she is viewed by employers as potentially pregnant. Therefore, the elimination of discrimination based on pregnancy in these employment practices in addition to disability and medical benefits will go a long way toward providing equal employment opportunities for women.

This same concern for the "potentially pregnant" woman was voiced throughout the legislative hearings,^{34/} and clearly evidences Congress' intent to prohibit employers from adopting policies which exclude women from jobs because of their biological role.

^{34/}See, e.g., Proposed Amendment to Title VII to Prohibit Sex Discrimination on Basis of Pregnancy: Hearing on H.R. 5055 & 6075 Before the House Labor Subcommittee on Employment Opportunities, 95th Cong., 1st Sess., 64 (1977) (statement of Dr. Czarnecki, American Citizens Concerned for Life) (women should not be discriminated against because they, not men, have the capacity to become pregnant); id. at 287 (statement of Bella Abzug) (women denied jobs and hired into less responsible positions because of pregnancy potential); id. at 135 (statement of Drew S. Days III, Assistant Attorney General, Civil Rights Division, Dept. of Justice) (loss of employment opportunities makes pregnant, potentially pregnant, and formerly pregnant women second class citizens); Proposed Amendment to Title VII to Prohibit Sex Discrimination on Basis of Pregnancy: Hearing on S. 995 Before Senate Labor Subcommittee, 95th Cong., 1st Sess., 392 (1977) (statement of Sen. Dick Clark) (discrimination against women on basis of capacity to become pregnant not consistent with Civil Rights Act's goals); id. at 32 (statement of Ethel Bent Walsh, Vice-Chair, EEOC) (employment policies directed at pregnant or potentially pregnant women one of most significant hindrances to women's labor market participation).

Unlike pregnancy, which is not a permanent condition and does not affect all women at all times, the capacity to bear children is an immutable sex characteristic which virtually all women have or are presumed to have for the greater part of their working lives. To hold that this is not a classification based on sex would mean that employment opportunities for women could be forever circumscribed by their biological role -- a result clearly contrary to Congress' goal of providing equal access to the job market for both men and women.^{35/}

Exclusionary policies affect all women employees in other significant ways. They subject all women to special scrutiny about their child-bearing intentions, sexual activities, and birth control methods and, thus, operate to invade their personal privacy in a most sensitive area. Any woman who remains in a restricted job is forced, per se, to publicly reveal her sterility. Men, on the other hand, are not asked when or if they intend to have children,

^{35/}The risk of injury to a future child from exposure levels that are within OSHA standards is undoubtedly less than the probability of injury to a child who is driven by automobile to and from school daily. Williams, supra n. 2, at 652, n. 75. The risk is also likely less than that associated with consumption of alcohol and coffee, and with the use of cigarettes during pregnancy, or with pre-conception exposure of parents of either sex to diagnostic x-rays. See generally, Williams, supra n. 2, at 652-53 & n. 76.

even though their exposure to toxic substances could also result in injury to a future child.^{36/}

An approach which would respect both privacy rights and health concerns of future parents would offer men and women full information and confidential counselling on potential hazards, plus voluntary temporary transfers during the period of potential risk. An employer minimally must treat similarly situated employees similarly, and either restrict both men and women from areas which pose a potential hazard to their future children or offer both the right to choose.

Supreme Court caselaw provides dispositive guidance. The attempt to avoid fetal harm (and any potential liability or cost), by excluding all fertile women, including many who will not become pregnant, is analogous to Los Angeles Dept. of Water & Power v. Manhart, 435 U.S. 702 (1978). In that case, the employer relied on sex-based actuarial tables in deducting larger pension contributions from the paychecks of women employees than those of men. The Court rejected the employer's reasons for this explicit discrimination, stating:

^{36/} Virtually all of these policies require women to prove affirmatively their physical incapacity to bear children in order to qualify for restricted jobs. This rule applies regardless of the marital status, sexual activity or birth control practiced by the woman employee.

The statute's focus on the individual is unambiguous. It precludes treatment of individuals as simply components of a racial, religious, sexual, or national class Individual risks, like individual performance, may not be predicted by resort to classifications, proscribed by Title VII.

Id. at 708,710. (Emphasis added.) In other words, the fact that women as a class share the child-bearing characteristic does not permit an employer to assume that an individual woman will bear a child.

In Manhart the generalization was accurate: women as a class do live longer than men as a class. In contrast, although most women are fertile for a significant part of their adult lives, most working women are not pregnant at any given point in time. See pp. 6 - 9, supra. However,

[e]ven a true generalization about the class is an insufficient reason for disqualifying an individual to whom the generalization does not apply [T]he statute requires that we focus on fairness to individuals rather than fairness to classes. Practices that classify employees in terms of religion, race, or sex tend to preserve traditional assumptions about groups rather than thoughtful scrutiny of individuals.

435 U.S. at 708-90.

Exclusionary policies incorrectly assume that fetal injury can only occur through maternal exposure after conception. Such stereotypes are even less defensible than the generalization in Manhart, which still provided an inadequate defense for a policy which treated "a person in a manner which but for that person's sex would have been different." Id. at 711. (Citation omitted.)

Likewise, in Phillips v. Martin Marietta Corp., 400 U.S. 542, the Supreme Court ruled that a policy excluding from employment women with pre-school age children, but not men with pre-school age children, violated Title VII absent proof that the policy could be justified as a bona fide occupational qualification ("BFOQ") under 42 U.S.C. § 2000e-2e.^{37/} That policy was based on a generalization that "conflicting family obligations" would interfere with the job performance of women with small children. The Court summarily rejected the proposition that such facial discrimination could be justified by reference to such unproven assumptions. Id. at 544.

^{37/}See pp. 24-30, infra, for a discussion of the applicability of the BFOQ defense.

Even a policy which does not explicitly discriminate against women, but which affects them predominantly or exclusively, may also run afoul of Title VII. Such policies - perhaps entitled "Avoidance of Reproductive Hazards" - unless applied equally to men also deny women employment opportunities solely because of their ability to become pregnant. Even prior to the amendment of Title VII in 1978, the Supreme Court recognized that a "neutral" policy, which adversely affects women (because of their ability to become pregnant) or imposes burdens on women which men do not suffer, violates Title VII.^{38/} Nashville Gas Co. v. Satty, 434 U.S. 136 (1977)

^{38/} Involuntary exclusion from employment cannot be deemed a "benefit" to women, even if the employer believes the policy is "for their own good," as demonstrated by the fact that the imposition of an exclusionary employment policy compelled some women to submit to surgical sterilization in order to secure their employment. Christman et al. v. American Cyanamid Co., No. 80-0024-P (N.D. W.Va.), Second Amended Complaint, ¶'s 33-35. Moreover, good intentions do not insulate employers from liability for discrimination, whether the policy takes the form of an overt sex-based classification or a neutral rule. For example, state protective laws which were designed specifically to "benefit" women by protecting them from arduous and dangerous work - sometimes also highly remunerative, interesting, and otherwise desirable - were nonetheless held to constitute unlawful discrimination under Title VII. Rosenfeld v. Southern Pacific Co., 444 F.2d 1219 (9th Cir. 1971). See also LeBlanc v. Southern Bell Telephone & Telegraph Co., 33 F. Supp. 602 (E.D.La. 1971), aff'd 460 F.2d 1228 (5th Cir.), cert. denied, 409 U.S. 990 (1972) and General Electric Co. v. Hughes, 454 F.2d 730 (6th Cir. 1972). The Fourteenth Amendment likewise prohibits sex-based classifications, even if the purpose of the classification is "to favor [women], not to disfavor them." Wengler v. Druggists Mutual Ins. Co., 446 U.S. 142, 150 (1980). See also Orr v. Orr, 440 U.S. 268, 283 (1979). The showing of intent to discriminate required in constitutional challenges is, of course, not imposed in Title VII cases. Compare, e.g., Nashville Gas Co. v. Satty, 434 U.S. 136 with Personnel Admin. of Mass. v. Feeney, 442 U.S. 256 (1979).

Satty indicates that pregnancy-based classifications which, prior to the "pregnancy amendment" were not viewed as per se discriminatory, were therefore "neutral" rules which violate Title VII if they have a "discriminatory effect." Id. at 141. By denying accrued seniority to women who had taken pregnancy leave:

. . . petitioner has not merely refused to extend to women a benefit that men cannot and do not receive, but has imposed on women a substantial burden that men need not suffer. . . . [Title VII does not] permit an employer to burden female employees in such a way as to deprive them of employment opportunities because of their different role.

Id. at 142.

Most exclusionary policies are either per se sex-based classifications or neutral policies which have a discriminatory effect and operate to burden women. Under either circumstance, Title VII requires that they be stricken unless properly justified by some recognized defense.

The BFOQ Defense

The sole defense available to an employer who adopts a policy which "explicitly discriminates against women on the

39 /

basis of their sex" is the BFOQ defense. Dothard v. Rawlinson, 433 U.S. 321, 332-33 (1977); Phillips v. Martin Marietta Corp., 400 U.S. at 544; Burwell v. Eastern Air Lines, Inc., 633 F.2d at 369-70. It is also settled that this defense "was . . . meant to be an extremely narrow exception to the general prohibition of discrimination on the basis of sex." Dothard v. Rawlinson, 433 U.S. at 334, Burwell v. Eastern Air Lines, Inc., 633 F.2d at 370, n. 15.

The criteria for judging a BFOQ defense was stated in Arritt v. Grisell, 567 F.2d 1267, 1271 (4th Cir. 1977):

[T]he burden is on the employer to show (1) that the bfoq which it invokes is reasonably necessary to the essence of its business (here the operation of an efficient police department for the protection of the public), and (2) that the employer has reasonable cause, i.e., a factual basis for believing that all or substantially all persons within the class (in our case, persons over 35 years old) would be unable to perform safely and efficiently the duties of the job involved, or that it is impossible or impractical to deal with persons over the age limit on an individualized basis.

39/Section 703(e) of Title VII provides that "notwithstanding any other provisions of this title, . . . it shall not be an unlawful employment practice for an employer to hire and employ employees . . . on the basis of bona fide occupational qualifications reasonably necessary to the normal operation of that particular business or enterprise." 42 U.S.C. § 2000e-2e.

To the same effect, see Weeks v. Southern Bell Telephone and Telegraph Company, 408 F.2d 228, 235-36 (5th Cir. 1969)

(physical effort required to perform the job was not a BFOQ justifying the employer's refusal to hire women); Diaz v. Pan American World Airways, 442 F.2d 385, 388-89 (5th Cir.), cert. denied, 404 U.S. 950 (1971) (the alleged inability of men to make airline passengers feel safe and comfortable was not a BFOQ justifying the employer's refusal to hire male flight attendants).

The exclusion of fertile women from restricted jobs cannot be justified as a BFOQ. There is absolutely no evidence that women of child-bearing capacity cannot perform the essential duties of the jobs from which they have been excluded. Nor is there any indication that corporate concern for fetal health goes to the "essence" of the business. While such a concern may be admirable if directed equally to all employees, it does not excuse discriminatory behavior:

[T]he argument that a particular job is too dangerous for women may appropriately be met by the rejoinder that it is the purpose of Title VII to allow the individual woman to make that choice for herself.

Dothard v. Rawlinson, 433 U.S. at 335. The following language, from an analysis of the "business necessity" defense in Title VII, is particularly apt:

[The employer's] contention that an element of business necessity is its consideration for the safety of the pregnant flight attendant and her unborn child is not persuasive. If this personal compassion can be attributed to corporate policy it is commendable, but in the area of civil rights, personal risk decision not affecting business operations are best left to individuals who are the targets of discrimination.

Burwell v. Eastern Air Lines, Inc., 633 F.2d at 271.

Safety considerations have only been upheld as the basis for a BFOQ defense when safety is an essential element of the job or business. See, e.g., Dothard v. Rawlinson, 433 U.S. at 335-36 (maleness constitutes a BFOQ when gender of female guards would threaten prison security); Condit v. United Air Lines, Inc., 12 E.P.D. ¶11,195, aff'd as not clearly erroneous. 558 F.2d 1176 (4th Cir. 1977), cert. denied, 435 U.S. 934 (1978) (nonpregnancy constitutes a BFOQ when incapacitation of pregnant flight attendants might threaten passenger safety); Usery v. Tamiami Trail Tours, Inc., 531 F.2d 224, 236-38 (5th Cir. 1976) and Hodgson v. Greyhound Lines, Inc., 499 F.2d 859, 864-65 (7th Cir. 1974), cert. denied sub nom. Brennan v. Greyhound Lines, Inc., 419 U.S. 1122 (1975), (age constitutes a BFOQ for bus driver position when driver's advanced age might threaten safety of passengers).

In contrast, exclusionary policies have no bearing on the execution of business functions or on the ability of the female employee to perform any of her job duties.

While health concerns figure prominently in the explanation for the adoption of exclusionary policies, companies clearly adopt such policies to avoid the possibility of any liability for injuries to some subsequently born child. However, there is no evidence that such liability would be likely or that its cost would be substantial or unduly burdensome. It is therefore to be assumed that no such evidence exists. Nashville Gas Co. v. Satty, 434 U.S. at 143. OSHA has concluded that compliance with the Lead Standard should "protect against the adverse effects of lead exposure" to persons planning children and should "minimize" "the risk of reproductive effects." 43 Fed. Reg. 52,960 (1978).

Moreover, the Supreme Court has rejected the proposition that cost alone is a defense to facial discrimination:

In essence, the Department is arguing that the prima facie showing of discrimination based on evidence of different contributions for the respective sexes is rebutted by its demonstration that there is a like difference in the cost of providing benefits for the respective classes. That argument might prevail if Title VII contained a cost-justification defense But neither Congress nor the courts have recognized such a defense under Title VII.

Los Angeles Dept. of Water & Power v. Manhart, 435 U.S. at 716

Even if cost considerations could provide a defense in certain circumstances, such circumstances have never been demonstrated with regard to exclusionary policies. If toxic workplace exposures might subject a company to liability to the future children of workers, that potential liability could extend equally to the children of male and female workers.^{40/} The notion that companies are exposed to different or greater potential liability to the future children of women workers is unsupported by fact and is based solely on remote speculation. This is particularly so with respect to women who do not intend to have (more) children or who have no immediate intention of having children and are taking reliable precautions to prevent pregnancy. While it is possible that one of these women could become pregnant and, despite warnings, not discover the pregnancy for some time,

^{40/}Lawsuits brought by male veterans who served in Viet Nam and were exposed to the herbicide "agent orange" exemplify this point. Some actions allege birth defects in subsequently born children, miscarriages, and "serious maladies in servicemen." See, e.g., "Five Makers of Agent Orange Charge U.S. Misused Chemical in Viet Nam: Companies Replying to Suit, Say Federal Negligence Is Responsible For Any Harm to Veterans and Kin," N.Y. Times, Jan. 7, 1980, § A, p. 14, col. 1. Male Workers at a plant in Rensselaer, N.Y. also allege that their exposure to the herbicide oryzalin has resulted in birth defects in their children. They have filed complaints with OSHA and the Environmental Protection Agency. "Union, Citing Birth Defects, Asks Ban On a Herbicide," N.Y. Times, Nov. 9, 1979, p. 16, col. 1.

and then give birth to an injured child, it is obvious that the possibility of any liability resulting from such an unusual chain of events would be extremely remote. One could just as easily speculate that a male worker exposed to a mutagenic substance would father a child with birth defects, that a pregnant female worker in a non-restricted area could be injured by an industrial accident, or that the leakage of toxic wastes could injure individuals in the outside community. E.g., Hooker Chemical Co. at Love Canal, Niagara Falls, N.Y.

Moreover, most companies are insured against a wide variety of potential injuries, including employee injuries and injuries to consumers and to persons in the community. Before the avoidance of any additional insurance costs could be considered a "compelling business purpose," there would have to be a showing that the additional insurance costs would be substantially greater than those already necessitated by normal business operations.

The "Business Necessity" Defense

Nor do exclusionary policies fare better if framed as neutral rules. Because they have a discriminatory impact on women employees, they must be justified by a showing of "business necessity" for the policy. In order to establish this defense,

the business purpose must be sufficiently compelling to override any racial impact; the challenged practice must effectively carry out the business purpose it is alleged to serve; and there must be available no acceptable alternative policies or practices which would better accomplish it equally well with a lesser differential racial impact.

Burwell v. Eastern Air Lines, Inc., 663 F.2d at 371 quoting Robinson v. Lorillard Corp., 444 F.2d 791,798 (4th Cir.), cert. dismissed, 404 U.S. 1006 (1971). Measured against this test, few, if any exclusionary policies can be sustained.

Women of child-bearing capacity are fully able to perform the jobs from which they have been excluded. No Company is in the business of protecting the health and safety of involuntary subjects - in this case the unconceived potential future children of workers.^{41/} Moreover, there is no "compelling" business-related purpose which is significantly enhanced by a policy whose goal it is to achieve "zero risk" for one miniscule segment of those potentially adversely affected by its use of toxic substances. Neither is the potential cost of non-discrimination a defense, if cost must be incurred to offer women a work environment equally healthy

^{41/}The parents, if fully informed of the risks, are in a much better position to protect the interests of their future children. Unlike the company, they are in a position to assess both the risks of remaining in their jobs and of leaving them - depending on whether comparable alternative employment is available.

as that provided to men^{42/} or to insure against newly-discovered risks. Moreover, no policy can be justified absent evidence that actual harmful exposure levels exist. Such an^{43/} admission would arguably constitute proof of an OSHA violation.

However, even if all this were not true, these policies are not defensible because they fail to serve their own purported goals effectively. It is clear that fetal health cannot be protected solely through health programs

^{42/}No evidence suggests that the fetus is more susceptible to injury in utero than from preconception paternal exposure to substances with gametotoxic or mutagenic effects. OSHA's findings upheld by the District of Columbia Court of Appeals, United Steelworkers of America v. Marshall, 647 F.2d at 1256-57, and the medical literature indicate this is not true. See pp.10-13 supra. Even if true, however, that fact would not excuse discrimination, since an employer would then be charged, under both the OSH Act and Title VII, with making the workplace safe for both sexes, even at some expense. See Los Angeles Dept. of Water & Power v. Manhart, 435 U.S. at 716-17 and United Steelworkers of America v. Marshall, 647 F.2d at 1238, n. 74 and 1256-57 and n. 96.

^{43/}29 U.S.C. § 654(a) states: "Each employer - (1) shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm. . . ."

^{44/}
 directed at women, and that potential liability, if any, may accrue to the children of exposed workers of both sexes. Yet, with reference to in utero exposure, some companies have adopted a "zero risk" standard, which is not adopted in any other situation. Similarly, the risks of fetal hazards from paternal exposure are disregarded or underestimated. There are no facts which would justify or even explain such a different standard where similar risks and interests are at issue.

Thus, there is no indication that exclusionary policies targetting women workers are even a minimally rational approach to a perceived (but not necessarily actual) problem. Absent a rational, "factual basis," Weeks v. Southern Bell Tel. & Tel. Co., 408 F.2d at 235, there can

^{44/}And see note 20, supra. See, e.g., Schmeck, "Genetic Flaws Can Come From Father," N.Y. Times, Feb. 24, 1980, § IV, p. 20, col.1, reporting that, although "birth defects, infertility, even the lack of male heirs generally have been blamed on women," new studies of children "with multiple birth defects" have "traced almost all to the paternal side of the child's inheritance." In particular, Down's Syndrome, once thought to be linked primarily to maternal factors, is now believed to involve paternal genetic contribution. Id.; Brody, "Sperm Found Especially Vulnerable to Environment," N.Y. Times, Mar. 10, 1981, § III, p. 1, col. 5, reporting that, "scientists are finding that a wide variety of environmental and industrial chemicals can interfere with the normal development of sperm and possibly cause birth defects and infertility."

be no argument that a policy, which segregates virtually all women employees and limits their employment opportunities, is "legitimate" or that is "sufficiently compelling" to override its discriminatory impact. Burwell v. Eastern Air Lines, Inc., 633 F.2d at 371 (citation omitted).^{45/}

Available Alternatives

Even assuming that the objectives underlying exclusionary policies were valid and business-related, there are alternative ways to protect against harm to future children of workers which do not entail the discriminatory exclusion of all fertile women.

The most obvious and optimal alternative is to reduce exposure to levels safe for workers of both sexes, which in any event is arguably required by the OSH Act. United Steelworkers of America v. Marshall, 647 F.2d at 1238, n. 74 and 1265, n. 96. Depending on the circumstances, this might be accomplished by the use of alternative substances, by job rotation plans, by minor alterations in the manu-

^{45/} [A]cceptance of [an employer's] policy cannot be predicated on the company officials' assertion of a bona fide belief that it is justified.

Burwell v. Eastern Air Lines, Inc., 663 F.2d at 374 (opinion of Butzner, C.J., concurring in part and dissenting in part).

facturing process, by the use of protective equipment, and so forth.

Further, most policies are not narrowly tailored to achieve their ostensible goals. There simply is no reasonable basis nor demonstrable need for treating all women who can become pregnant as if they are pregnant. Women, once they are fully informed as to workplace hazards, can be trusted to take reliable precautions to avoid unplanned pregnancies and to detect any pregnancy at an early stage. Presumably men, also, if informed, could be relied upon to undertake reasonable precautions to protect their future children.

Equally effective would be a policy which excludes from truly hazardous jobs only those workers, of either sex, who are actually planning pregnancies and which provides all employees with educational material, voluntary medical monitoring, and job transfer provisions and seniority protection for employees in such jobs who wish to have children. OSHA has adopted this approach in the Lead Standard, and its feasibility and reasonableness has been upheld. United Steelworkers of America v. Marshall, 647 F.2d at 1228-38.

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Conclusion

Exclusionary policies require women workers to elect between their jobs and their fertility. If they wish to preserve their right to bear children, they must forego their jobs; if they wish to retain their jobs, they must sacrifice their ability to have children.

Women workers are being required to make this agonizing decision even where the "risk" associated with their employment is wholly speculative or less, for example, than that posed by drinking coffee or alcoholic beverages or smoking cigarettes.^{46/} The risk they face is surely less than that faced daily by couples with known genetic or other characteristics which increase the chance that their children may be born with Down's Syndrome, hemophilia, Tay-Sachs disease, sickle cell disease, Huntington's Chorea, or similar condition. Yet in all these situations, it is the right of the parents to choose. Why should it be different for women workers?

The alleged potential liability is not a sufficient explanation. Even if the children of women workers were the only source of potential liability - a proposition which is demonstrably false - it would be anomalous from a public

^{46/}See, e.g., Williams, supra note 2, at p. 653, n. 76.

policy vantage to permit companies to avoid the consequences of their potentially tortious conduct by allowing them to infringe their women workers' civil rights. The purpose of liability is to compensate the injured party for foreseeable harms and to deter future harmful conduct. The company which adopts an exclusionary policy purportedly foresees a harm (and thus arguably violates the OSH Act and commits a tortious act), but claims that it should be entitled to avoid responsibility for the consequences of its own acts (the use of toxic substances in a profit-making business) by depriving its women workers of their federally-secured rights. Thus they propose that two wrongs should make a right.

While there may not be one easy solution for every situation, there are certain important principles which must be accommodated to conform with existing law. First, women may not be limited in their employment opportunities and, second, workers should not be subjected to known hazardous health conditions where they can be avoided. Failure to enforce the principle of equality will reward and encourage discrimination, especially where health policies are a subterfuge for intentional discrimination or where they merely indicate stereotypical reflexive thinking. If an employer has evidence of a hazard to a fetus in utero and evidence of other kinds of injuries to adult workers of both

sexes, sanctioning exclusion of pregnant women would be counter productive. The women will have lost their right to equality and their jobs, or they will have lost their fertility. The men will have lost the right to a safe workplace. The employer will have lost the incentive to provide a clean workplace, since the responsibility and burden will have been shifted to the employees. If we are concerned about the health of future generations, we cannot permit this result, since we know that exposure of male workers to toxic substances will have unforeseeable genetic consequences.

Secondly, we cannot afford to accept the principle that a "susceptible" class of workers can be treated differently. Women and blacks, two groups traditionally subjected to discrimination, have been the target of protective health policies which limit their employment rights. While it may appear that women are unique, since only they bear children, that misses the point for two reasons. One, we know that reproductive outcome can be affected by male exposure. Second, potentially, all identifiable groups have unique characteristics upon which differential treatment could be based. It may be that blacks or hispanics or Asian Americans have genetic characteristics which make

them more "susceptible" to certain chemicals and which result in genetic changes which are transmitted to future generations. Thus, the rights of all workers may be jeopardized by any approach which permits discriminatory exclusions of allegedly susceptible groups.

Insistence on equality of treatment will have a salutary effect on both the health of workers and their offspring. Men and women equally need and are entitled to the assurance that their children will not be adversely affected by their working conditions and that their work will not deprive them of their procreative potential. It is to be hoped that the initial focus on women's alleged "susceptibility" to certain hazards will ultimately produce the realization that women are not unique in this respect, and that both sexes need protection. I believe that this result will be stimulated by insistence on the principle that women's right to work cannot be made the price for their safety.

Mr. GORE. Thank you very much.

We will withhold questions until the other two members of the panel have completed their statement.

Dr. Hunt, we are honored to have you with us. You have had a great deal of experience with these different issues and we appreciate your coming to help us with them.

Dr. HUNT. Thank you.

I found as I read your original letter of invitation that the phrases which jumped out of the page at me were the relevant criteria for evaluating scientific legitimacy of screening programs in the work place.

They will form the basis for my presentation here to you today.

The way we have been looking at the tests that are used or the programs that are used bears some close scrutiny and I was pleased to hear from your opening comments this morning that this matter was also approached yesterday.

Today we are very particularly concerned with the reproductive system and it does have considerably more complex issues related to it, not the least of which is the array of physiologic end-points that are associated with the reproductive system.

When we started out on this concern for reproductive capacity, reproductive health in the work place, it was a very simple concept we all had and many of us in this room have been through the experience of the last six years of starting out being particularly and centrally concerned with the pregnant woman in the work place. We then progressed through a series of mutual head bangings to reach the state that we are at today in which we are really seeing that the reproductive system of the human species also includes male and female reproductive capacity and the associated physiologic functions.

We are not thinking of an area as simple as carcinogenesis, even though we are saying there are many different kinds of cancer with different kinds of causes. We have a general expectation which may not be right in the end, that there is an underlying fundamental cancer process that eventually will be elucidated.

In contrast, as we look at the reproductive system, we are examining the development of the reproductive system in the young, prepuberty. We are looking at the different development between the sexes post—or even from prepuberty into the reproductive period and all of these represent quite different physiologic functions.

It means, therefore, that any damage to them at any stage may appear in a different way. There is not going to be a fundamental underlying process that will explain how we look at the reproductive system.

As those of us who have been concerned with this in industry and academia, in the halls here and in Federal agencies, have grappled with this problem, we had to change our views as well. We were not just dealing with a pregnant woman in a workplace. There came to be a whole series of meetings held, workshops, gatherings to try to deal with this wider perception.

I have listed in my testimony the five immediate meetings of the last year or so which have attempted to deal with some of the questions that you have raised here. The one I mention particular-

ly in my testimony was that held just this last month by the Interagency Regulatory Liaison Group of the five regulatory agencies involved in that organization.

We are starting to get to a stage where there is some overall sensible way of looking at the total problem. I don't think we are now all floundering with a point of view that we are only concentrating on one area or another.

The listing that I provided in my testimony is my interpretation of—having attended three of those five workshops and being involved in several of the others—the likely usefulness and reliability of tests that can be used to assess the reproductive health of people.

I did not say used as screening for screening programs. I go back then to what I said about the relevant criteria for evaluating scientific legitimacy because even though we now have a list of several pages of potential tests, I would point out that most of them, unless they are of a very direct nature, are not universally agreed upon in the scientific community and the argument that I have made, as you can read it, is that among scientists, there are marked differences in assessment of the legitimacy of an approach.

There is the issue of how legitimate is the scientific testimony once established, once you apply it to use on human populations.

I had not included an example in my testimony and about the only one that I could come up with was that a sound scientific epidemiologic approach was being applied to the Tallahassee syphilis study but, indeed, its application to the human condition certainly was not appropriate to the scientific approach.

So that these two concepts of what is scientific legitimacy need to be kept in mind. It is my perception we have oftentimes gotten those two things terribly mixed up and have ended up having impressions and conclusions on scientific legitimacy in the true scientific sense overly affected by the other and vice versa.

So what I would like to give you, and expand on a little from my written testimony here, are some of the examples that we see in the work setting where we are starting now to see where there are very specific well-known impacts of hazards and how we look at those.

The best understanding that we have in many instances are of biological hazards which relate to infection—and we have a continuing potential serious problem in hospitals of the infection of the newborn with rubella and the outbreak of rubella as an infection in the hospital—this I presented as the most well-known example of a hazard which will result in congenital anomalies in a child, in the newborn when the mother is infected.

If she was infected during the first trimester, there is high probability that up to 22 percent of the babies of those pregnancies will have severe congenital abnormalities. If she was infected during the second trimester, it would be 10 percent.

This I look on in some ways as comparable to the probability that is frequently talked about of severe accident, either a severe accident in the laboratory or in a nuclear reactor. We have always the possibility of a severe accident, namely outbreak of infection, be it rubella or forms of infectious hepatitis, which if you started to

look at that issue, is one of our ticking time bombs, either for hospitals or anywhere else.

So we are saying that in this instance from a rubella infection, the accident potential is as extreme or as likely as in any other kind of accident.

We know very specifically and quantitatively what the outcome is likely to be. Yet we do not have across this country a universal appreciation or responsibility from hospital administrators or whoever is responsible from the institutional level up through the State to the Federal level to insure that individuals who are working in hospitals be immunized or even tested for their immune status in relation to rubella.

The opposite end of this is the extent to which hospital personnel can infect pregnant women, patients attending prenatal clinics. That particular example has happened just in the past 2 years with a male obstetric resident who contracted rubella and proceeded to expose 200 pregnant women to rubella.

This occurred because a very large hospital in California did not have any screening program for their workers.

Right to this day—we can check with Joan as to whether she knows the details on this and Jeanne may know—but as far as I am aware, New York State right now still only demands screening of women hospital employees, and they are further ahead than most States.

Indeed, they are acknowledging perhaps the fact that a danger exists for women who may become pregnant who contact rubella.

There is sound scientific knowledge upon which there is very little controversy and still falls into some of the same categorizations that Joan laid out.

Where is the consistency for an appropriate protection of workers and their offspring? When we move to physical phenomena such as radiation, be it ionizing radiation or not, we also have inconsistencies. We do have sound scientific agreed-upon knowledge from both animal observations and from human observations of the effect of ionizing radiation and nonionizing radiation on spermatogenesis.

This has been so long known that back in the 1930's, ionizing radiation was used as a means for sterilizing males therapeutically.

There is a very strong feeling in many sectors that because radiation is something that is feared, that all women of child-bearing age should be excluded therefrom except when we come to the hospital, where the same level of concern is often not evident.

The scientific underpinning is that rapidly dividing cells are more vulnerable to ionizing radiation than other cells, such as brain cells, and what we see in any radiation unit as the most rapidly dividing cells are the cells of the testes and if there is, indeed, a pregnant woman present, the cells are those of the embryo. I would submit that under the usual operating practices of a well-controlled hospital setting, in a radiology department with the appropriate badging, the appropriate monitoring of what radiation dose has accumulated over weeks and months, that there are appropriate working practices and shielding that can be applied to both situations, shielding that can be applied to the male in terms

of the rapidly dividing cells of the testes, and can be applied to the women in terms of the development of the embryo.

When we move into the chemical area, it becomes more complex; in large measure because we have very little information that is comparable to the first two examples that I have given so far. We are essentially in an area where we know a much lesser amount.

The most quantitative reliable information that we have, I think, right now, again relates to the hospital setting with the use of anesthetic gases and the evidence that we have both for carcinogenicity and adverse effects on reproduction.

In that instance, we now have in general use gas scavenging controls, at least in hospitals. We don't have quite as much control in dental offices.

I have commented in my prepared remarks on "the big black hole," as I see it, on the developing reproductive system which involves 10- and 11-year-old children.

These are the children that the amendments to the Fair Labor Standards Act has allowed to work at hand-harvesting short-term crops. The critical underlying scientific information about which we can't even argue, because we don't have any, is what is the impact of a toxic environment on the reproductive development of a 10- or 11-year-old child where we are looking from that age up to 13 to 14 at the doubling and trebling of the weight of the ovaries, the doubling or more of the testes, a period of critical development for the future reproductive health of individuals.

Now I will go over very briefly the answers that I have to your questions because what I have said so far, I think, is an effort to impress the importance of the scientific validity of tests and how we use that information, and apply the tests appropriately to the work situation.

We are in a very difficult situation of matching up our scientific world with our legal world and knowing that some of the expectations of proof can vary in the scientific arena from that which we see in the legal arena.

Where we are going to go from here is not particularly clear. I came to that particular conclusion some months ago as we all watched the Love Canal tragedy that, when it actually came to the crunch, when it actually came to a full assessment of what should be done in that situation, scientists could not agree on the validity or the usefulness of any single test to establish whether that particular population—and we can look on the women in that community as working in their homes—what were the particular characteristics of that population or what were the particular tests that could be used to evaluate them.

That experience points out, then, the dilemma we face. I have listed in my testimony several pages of potential tests that can be used.

Do I have any confidence at all that any one of them will be universally acceptable to the scientific community for a screening of any population and quite frankly, I think at this point, I don't have a high expectation that any one of them will be.

Why do I say that? I say it because we do not operate in a completely scientific environment in this country right now. There is always some good social reason why—there is always some other

reason why somebody, be it a scientist or the public, will not believe the results of the tests. It means, then, that both sides can play the game, that you do not necessarily wish to believe without any question the results of a certain study.

This gets us in the dilemma of whether we are impugning science as a philosophy or whether we are saying that all sides of a question must remain open at all times. But that leads us almost to being incapacitated. It leads us to being unable to make decisions about what to do.

I am not answering a question very well to you today when I say I don't have a great deal of confidence that one or more of the tests that I have listed will reach universal acceptance.

We may be able to move to a situation of better confidence among the scientific community that a test or several tests are going to be more useful than others, but unless we improve that mutual self-confidence among scientists, I think we are going to continue having the kind of unproductive discourse that goes on when we have a situation like Love Canal.

We may have a similar situation that will erupt in an industrial setting before long where, indeed, we never come to a resolution of what tests would be the most useful to assess the impact of an adverse environment on that population.

I am even wondering whether, indeed, we are already at that stage where we cannot get an agreement as to whether we should screen or not screen, whether we have tests that are useful to screen or not screen and whether we can honestly decide who should be in the workplace and who should not and whether we even have a right to say that.

[The prepared statement of Ms. Hunt follows:]

STATEMENT OF
VILMA R. HUNT
ASSOCIATE PROFESSOR OF ENVIRONMENTAL HEALTH
THE PENNSYLVANIA STATE UNIVERSITY

BEFORE THE

HOUSE COMMITTEE ON SCIENCE AND TECHNOLOGY
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
WASHINGTON, D.C.

OCTOBER 15, 1981

I AM VILMA R. HUNT. I HAVE BEEN ASSOCIATE PROFESSOR OF ENVIRONMENTAL HEALTH AT THE PENNSYLVANIA STATE UNIVERSITY FOR THE PAST TEN YEARS. FROM DECEMBER 1978 TO MAY 1981, I WAS ON LEAVE TO SERVE WITH THE ENVIRONMENTAL PROTECTION AGENCY, FOR ONE YEAR WITH THEIR SCIENCE ADVISORY BOARD, AND FOR ALMOST TWO YEARS AS THE DEPUTY ASSISTANT ADMINISTRATOR FOR HEALTH RESEARCH IN THE OFFICE OF RESEARCH AND DEVELOPMENT. TODAY I SPEAK TO YOU AS A PRIVATE CITIZEN, WHOSE TESTIMONY IS BASED UPON PERSONAL KNOWLEDGE AND EXPERIENCE.

FIRST, I WOULD LIKE TO COMMEND YOU, CONGRESSMAN GORE AND YOUR STAFF FOR THE PERCEPTIVENESS YOU HAVE BROUGHT TO THE FORMULATION OF THE QUESTIONS - WHICH YOU EXPECT US TO ANSWER. MY RESPONSIBILITY IS TO APPLY YOUR QUESTIONS TO HUMAN REPRODUCTION AND THE SCIENTIFIC ISSUES RELATED TO IT. AT THIS POINT I AM NOT SATISFIED WITH MY ANSWERS AND MY PREAMBLE IS, IN PART, AN EFFORT TO EXPLAIN WHY DEFINITIVE ANSWERS TO SUCH QUESTIONS ARE ELUSIVE - PARTICULARLY IN THE CONTEXT OF THE REAL WORLD OF THE WORKPLACE.

YOUR AIM IS TO EXAMINE THE RELEVANT CRITERIA FOR EVALUATING THE SCIENTIFIC LEGITIMACY OF MEDICAL AND GENETIC SCREENING PROGRAMS IN THE WORKPLACE. THE TERM SCIENTIFIC LEGITIMACY IS LOADED. SOME ASSUME THAT ALL SCIENCE, BY DEFINITION, IS LEGITIMATE AND THE INTRODUCTION OF CRITERIA EXTERNAL TO THE SCIENTIFIC APPROACH INSTANTLY MAKE THE SCIENCE ILLEGITIMATE AND UNUSEABLE. FOR EXAMPLE, EPIDEMIOLOGY AS A DISCIPLINE (OR ART FORM) COMES UNDER INTENSE CRITICISM FROM THOSE SCIENTISTS

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WHO PREFER THE LABORATORY MODEL TO ESTABLISH CRITERIA FOR THE EVALUATION OF SCIENTIFIC AND MEDICAL STUDIES. HUMAN POPULATIONS SELDOM, IF EVER, PROVIDE CONDITIONS FOR IDEAL STUDY DESIGN AND THE VALIDATION OF FINDINGS BY SUBSEQUENT STUDIES.

THE IMPORTANCE OF THIS FIRST INTERPRETATION RELATES TO THE CONTROVERSIES AMONG SCIENTISTS CONCERNING THE DEVELOPMENT AND VALIDATION OF MEDICAL AND GENETIC SCREENING METHODS.

A SECOND INTERPRETATION IS EQUALLY IMPORTANT IN THAT CONTROVERSIES BETWEEN AND AMONG SCIENTISTS AND THE PUBLIC FREQUENTLY REVOLVE AROUND HOW WELL THE PUBLIC UNDERSTANDS THE APPLICABILITY OF A PARTICULAR SCIENTIFIC METHOD OR MEDICAL PROGRAM TO THEIR NEEDS. THAT IS, THE TERM SCIENTIFIC LEGITIMACY CAN ALSO REFER TO THE INTERPRETATION OF SCIENTIFIC METHODS AND PRINCIPLES AS THEY RELATE TO THE HUMAN CONDITION IN A SOCIAL SETTING. THEN WE MUST USE CRITERIA APPLICABLE TO THE TRANSFER OF KNOWLEDGE AND JUDGMENT - FROM A CONTROLLED SETTING TO ONE WITH EXTERNALITIES, OFTEN OVERWHELMING EXTERNALITIES, FROM SCIENTISTS TO THE LAY PUBLIC.

I BELIEVE BOTH INTERPRETATIONS OF THE TERM SCIENTIFIC LEGITIMACY CAN HELP IN ANSWERING THE QUESTIONS YOU HAVE POSED.

THE REPRODUCTIVE SYSTEM PRESENTS A COMPLICATED ARRAY OF VULNERABLE TARGETS THROUGHOUT THE LIFESPAN OF AN INDIVIDUAL.

IN RELATION TO THE WORKPLACE, THE CENTRAL CONCERNS ARE PROCREATIVE CAPACITY, THE INTEGRITY OF THE FERTILIZED OVUM, AND ITS SUBSEQUENT NORMAL DEVELOPMENT.

OVER THE PAST YEAR THERE HAVE BEEN THREE WORKSHOPS DEALING SPECIFICALLY WITH RISK ASSESSMENT OF REPRODUCTIVE HAZARDS, A REPORT FROM THE COUNCIL ON ENVIRONMENTAL QUALITY ON CHEMICAL

HAZARDS TO HUMAN REPRODUCTION AND PUBLICATION OF PROCEEDINGS OF A 1978 WORKSHOP ON METHODOLOGY FOR ASSESSING REPRODUCTIVE HAZARDS IN THE WORKPLACE SPONSORED BY THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH. THE MOST RECENT WORKSHOP WAS LESS THAN A MONTH AGO AND WAS SPONSORED BY THE INTERAGENCY REGULATORY LIAISON GROUP (I UNDERSTAND NOW DEFUNCT).

SCIENTISTS FROM UNIVERSITIES, INDUSTRY, LABOR, REGULATORY, AND NON-REGULATORY AGENCIES OF THE FEDERAL GOVERNMENT HAVE PARTICIPATED IN ALL FIVE OF THESE ENDEAVORS. I HAVE PERSONALLY PARTICIPATED IN THREE OF THE FIVE, AND CONTRIBUTED TO THE PLANNING OF A FOURTH. MY REMARKS TODAY VERY MUCH REFLECT THE ACCUMULATED EXPERIENCE I HAVE ENJOYED INTERACTING WITH THIS LARGE NUMBER OF PARTICIPATING SCIENTISTS. YOU ARE HEARING MY INTERPRETATION OF THESE - OFTENTIMES INTENSE - DISCUSSIONS. AND I ACCEPT THE RESPONSIBILITY FOR ANY MISREPRESENTATION THAT MAY HAVE SLIPPED IN.

IN MY VIEW WE ARE NOW AT A STAGE WHERE WE CAN IDENTIFY THOSE REPRODUCTIVE END-POINTS ABOUT WHICH ENOUGH IS KNOWN TO ALLOW A FEW JUDGMENTS CONCERNING RISK ASSESSMENT. RISK ASSESSMENT, OF COURSE, IS THE IMPORTANT INTERMEDIATE STEP BETWEEN A SCIENTIFIC OBSERVATION/CONCLUSION AND THE SUBSEQUENT POLICY DETERMINATION, WHICH THEN AFFECTS INDIVIDUAL WORKERS OR GROUPS OF WORKERS.

TABLES 1 AND 2 REPRESENT A SUMMARY OF TESTS PRACTICAL TO PERFORM, IN ANIMALS AND HUMAN POPULATIONS TO ASSESS ADVERSE EFFECTS ON PROCREATING MEN AND WOMEN AND THEIR OFFSPRING.

TABLE 1

TESTS GENERALLY VIEWED AS APPROPRIATE
FOR SCREENING OF TOXIC SUBSTANCES

PATERNAL EFFECTS - REPRODUCTIVE END-POINTS

<u>ANIMAL</u>	<u>PRACTICAL TO PERFORM</u>	<u>USEFUL FOR HUMAN RISK- ASSESSMENT</u>
A. INDICES OF FERTILITY		
1) TESTES WEIGHT	+	+
2) TESTES HISTOLOGY	+	+
B. SPERM		
1) DENSITY, MOTILITY, MORPHOLOGY	+	+
2) FERTILIZING CAPACITY (IN HOMOLOGOUS OR HAMSTER EGG)	R & D	?
<u>HUMAN</u>		
A. EPIDEMIOLOGY - FERTILITY QUESTIONNAIRES, ETC.	+	+
B. CLINICAL MEASURES		
1) SPERM VOLUME, COUNT, MOTILITY & MORPHOLOGY	+	+
2) BLOOD HORMONE LEVELS	+	?
3) FERTILIZING CAPACITY HAMSTER EGG	R & D	+
4) ACROSIN	R & D	?
5) CERVICAL MUCUS PENETRATION	+	?
6) DNA HETEROGENEITY	R & D	?
7) YFF	R & D	?

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TABLE 2

TESTS GENERALLY VIEWED AS APPROPRIATE FOR SCREENING OF TOXIC SUBSTANCES		
MATERNAL EFFECT/OFFSPRING EFFECT - REPRODUCTIVE END-POINTS		
	PRACTICAL TO <u>PERFORM</u>	USEFUL FOR HUMAN RISK- <u>ASSESSMENT</u>
<u>ANIMAL</u>		
A. INDICES OF FERTILITY		
1) IMPREGNATION	+	+
2) CONCEPTION		
A) PRE-IMPLANTATION	+	+
B) POST-IMPLANTATION	+	+
3) LITTER SIZE	+	?
4) ESTRUS CYCLE	+?	?
B. DURATION OF GESTATION/DELIVERY	+	+
C. VIABILITY	+	+
D. BODY WEIGHT	+	?
E. VAGINAL OPENING	+	?
F. POSTNATAL EVALUATION		
1) REPRODUCTIVE CAPACITY	+	+
2) OTHER SYSTEMS (BEHAVIOR, CNS, ETC.)	R & D	?

TABLE 2, CONTINUED

	<u>PRACTICAL TO PERFORM</u>	<u>USEFUL FOR HUMAN RISK- ASSESSMENT</u>
<u>HUMAN</u>		
A. EPIDEMIOLOGY - FERTILITY MEDICAL RECORDS QUESTIONNAIRES	+	+
B. 1) EARLY SPONTANEOUS ABORTIONS, HCG IN MONTHLY URINES	+	+
2) BLOOD HORMONE LEVELS	+	R & D
3) DURATION OF GESTATION	+	+
4) PARTURITION	+	+
5) BIRTH WEIGHT	+	+
6) NEONATAL DEATH	+	+
7) CONGENITAL ANOMALIES	+	+
8) ALTERED SEX RATIO	+	+
9) CHILDHOOD CANCER	+	+
10) LACTATION		
CHEMICAL CONTAMINATION	+	+
MILK PRODUCTION	?	?

? SIGNIFICANCE OF TEST/OBSERVATION FOR HUMAN RISK ASSESSMENT
NOT CLEAR.

R & D STILL UNDER DEVELOPMENT/NOT YET VALIDATED.

+? PRACTICALITY WITHIN MULTIPLE TESTING SITUATIONS NOT
ESTABLISHED.

THE CHOICE OF ANIMAL SCREENING TESTS USEFUL FOR HUMAN RISK ASSESSMENT WAS BASED ON THEIR SENSITIVITY AND RELIABILITY FOR OBTAINING ACCURATE RESULTS. IT IS OBVIOUS FROM THE LIST THAT VIRTUALLY ALL OF THEM DEPEND ON DIRECT OBSERVATION. THOSE TESTS DEPENDING UPON MORE SOPHISTICATED EXPERIMENTAL METHODS, WHICH ARE INCLUDED, ARE ALL VIEWED AS STILL REQUIRING REFINEMENT AND VALIDATION. MY VIEW IS THAT IT IS NOT ACCIDENTAL THAT THOSE TESTS GENERALLY JUDGED SUITABLE ARE CONFINED TO DIRECT (AND CLOSE TO UNEQUIVOCAL) OBSERVATION, WHICH DEFIES QUESTIONING OF RESULTS (OTHER THAN IN TERMS OF INCOMPETENT LABORATORY MANAGEMENT OR FRAUD). WE CAN ASK, WHAT ARE THE LIMITATIONS OF THE OTHER TESTS, E.G., POST-NATAL EVALUATION OF CENTRAL NERVOUS SYSTEM DEVELOPMENT OR THE FERTILIZING CAPACITY OF SPERM USING HOMOLOGOUS OR HAMSTER EGG - TO NAME BUT TWO OF A WHOLE MYRIAD OF KNOWN TESTS. THE LATTER TEST OF FERTILIZING CAPACITY IS STILL VIEWED BY MANY SCIENTISTS AS BEING UNDER DEVELOPMENT WITH FURTHER NEED FOR VALIDATION, AND IN THE LABORATORY SITUATION WITH ANIMALS, SUCCESSFUL IMPREGNATION OF THE FEMALE IS A MORE RELIABLE APPROACH. IN THE CASE OF WORKERS, SOME CONSIDER IT TO BE A POTENTIALLY USEFUL TEST FOR AN INDIVIDUAL WHO HAS HAD KNOWN EXPOSURE TO A REPRODUCTIVE TOXIN. IN THE CASE OF POST-NATAL DEVELOPMENT OF THE CENTRAL NERVOUS SYSTEM FOLLOWING PRENATAL EXPOSURE THERE IS MORE THAN ENOUGH EXPERIENCE AMONG NEUROTOXICOLOGISTS TO COMPARE THE ANIMAL AND HUMAN DATA AND TO BEGIN TO VALIDATE TESTS WHICH CAN BE APPLIED TO HUMAN POPULATIONS. NEUROTOXICOLOGICAL TESTS ARE A GOOD EXAMPLE OF THE CONTROVERSY AMONG SCIENTISTS AS TO WHEN A METHODOLOGY IS OR IS NOT READY

FOR ROUTINE USE, OR FOR USE IN A SETTING WHERE RISK ASSESSMENT EFFORTS ARE BEING MADE. WHEN THE GENERAL POPULATION OR A CONTROL POPULATION BEING USED FOR COMPARISON SHOWS A WIDE RANGE OF VARIATION, THE STATISTICAL RIGOR OF THE RESEARCH DESIGN BOTH THEORETICALLY AND PRACTICALLY IS ASSESSED QUITE DIFFERENTLY FROM ONE SCIENTIST TO ANOTHER. THERE ARE THOSE WHO VIEW A SLIGHT BUT STATISTICALLY SIGNIFICANT DIFFERENCE BETWEEN TWO POPULATIONS AS INSUFFICIENT FOR ADEQUATELY ASSESSING RISK. OTHERS, WHO MAY BE VERY SOPHISTICATED IN THE TECHNIQUES FOR OBTAINING SUCH DATA WOULD PROBABLY BRING A DIFFERENT INTERPRETATION TO THE SAME DATA. WE CAN THROW THE NAIVE SCIENTIST INTO THIS MIX AND HE BECOMES AN EMBARRASSMENT TO BOTH SIDES.

WHEN WE MOVE TO THE HUMAN OBSERVATIONS IN TABLES 1 AND 2 WE ARE VIRTUALLY CONSTRAINED TO THE EPIDEMIOLOGICAL APPROACH WITH ALL ITS LIMITATIONS. FOR EXAMPLE, OBSERVATIONS ON SPERM QUALITY AND QUANTITY ARE PRIMARILY LIMITED BY THE EXTENT TO WHICH WE KNOW THE RANGE OF NORMALITY WITHIN THE POPULATION AT LARGE. THE DEVELOPMENT OF EPIDEMIOLOGICAL METHODS FOR EVALUATING MALE FERTILITY HAS BEEN GOING FORWARD MOST SUCCESSFULLY AT NIOSH FOR THE PAST 3 OR 4 YEARS. DESPITE THE LONG EXPERIENCE EPIDEMIOLOGISTS HAVE HAD DEALING WITH PREGNANCY OUTCOME, THERE IS LITTLE IMPROVEMENT IN TABLE 2 FOR FEMALE REPRODUCTIVE END-POINTS OVER THOSE FOR THE MALE IN TABLE 1.

THE INTEGRITY OF THE PREGNANCY ITSELF AS AN INDICATION OF FERTILITY CAN BE AN ELUSIVE END-POINT - BUT EVIDENCE OF EARLY PREGNANCY IS NOW POSSIBLE TO OBTAIN, AND THUS ALLOWS MORE RELIABLE OBSERVATIONS ON EARLY SPONTANEOUS ABORTIONS. OTHER

OBSERVATIONS OF THE EMBRYO/FETUS/INFANT ARE POSSIBLE, BUT THE EPIDEMIOLOGIC LIMITATIONS OF SAMPLE SIZE AND EXPOSURE HISTORY ARE THE MOST SERIOUS LIMITATIONS FOR ANY CLEAR-CUT ANSWERS. END-POINTS RELATING TO THE OFFSPRING DEPEND ON THE EXTENSIVE VITAL STATISTICS REPORTING SYSTEM, WHICH, UNLESS MAINTAINED AS A HIGH QUALITY RESOURCE BY THE NATIONAL CENTER FOR HEALTH STATISTICS, WILL IN THE FUTURE UNDERMINE THE INTEGRITY OF STUDIES IN THIS AREA. MATERNAL CHARACTERISTICS OF PARTURITION AND LACTATION HAVE BEEN OF LITTLE INTEREST IN THE UNITED STATES.

THE CONTEXT OF MY REMARKS SO FAR HAS BEEN PURPOSEFULLY IN RELATION TO THE METHODS USED FOR SCREENING TOXIC SUBSTANCES, ALTHOUGH YOUR AIM HERE TODAY IS TO EXPLORE MEDICAL AND GENETIC SCREENING IN THE WORKPLACE - THAT IS, SCREENING OF INDIVIDUAL WORKERS OR GROUPS OF WORKERS.

I HAVE DISCUSSED THE PROBLEM OF SCIENTIFIC AGREEMENT ON THE VALIDITY OF METHODS FOR SCREENING CHEMICALS, AND HAVE INFERRED THAT THE DISAGREEMENTS ARE INHERENT TO THE SCIENTIFIC METHOD AS WELL AS THE SCIENTIFIC COMMUNITY ITSELF. THE ASSUMPTIONS WE BRING TO THE WORKPLACE TO ASSESS THE RISK OF ADVERSE EFFECTS ON WORKERS OR PARTICULAR WORKERS ARE BASED UPON THE SCIENTIFIC LEGITIMACY OF THE RELATIONSHIP BETWEEN THE REPRODUCTIVE END-POINTS AND EXPOSURE TO THE ADVERSE ENVIRONMENT. IT IS REASONABLE THEN, TO CONCLUDE THAT SCREENING PROGRAMS AFFECTING WORKERS SHOULD BE DIRECTLY DEPENDANT ON TESTS THAT HAVE SCIENTIFIC LEGITIMACY.

WE ARE CONCERNED THAT THE PROCREATIVE INTEGRITY OF WORKERS, WHATEVER THE WORK SETTING, SHOULD REMAIN UNIMPAIRED. THE LISTED END-POINTS (TABLES 1 AND 2) RELATING TO REPRODUCTION CAN BE CONSIDERED TO TEST ON FIRM SCIENTIFIC BASES EVEN THOUGH RISK ASSESSMENT QUANTITATIVELY OR QUALITATIVELY MAY NOT YET BE A RELIABLE PROCEDURE. THE WORKER MAY BE EXPOSED TO BIOLOGICAL, PHYSICAL, AND CHEMICAL HAZARDS, AND WE DO HAVE EXAMPLES FROM EACH OF THESE CATEGORIES WHICH RELATE TO REPRODUCTIVE EFFECTS AND INVOLVE SCREENING OR MONITORING OF WORKERS.

THE BEST UNDERSTOOD IS THE BIOLOGICAL HAZARD IN HOSPITALS, PARTICULARLY NEWBORN NURSERIES, WHERE THERE IS A RECOGNIZABLE PROBABILITY THAT A NEWBORN WITH RUBELLA CAN INFECT A PREGNANT HOSPITAL WORKER. FOR THIS EXAMPLE, WE HAVE SOUND QUANTITATIVE DATA FOR RISK ASSESSMENT TO ESTIMATE THAT FOR PREGNANT WOMEN INFECTED DURING THE FIRST TRIMESTER, ABOUT 22% OF THE BABIES BORN WILL HAVE SEVERE CONGENITAL ABNORMALITIES, AND FOR INFECTION DURING THE SECOND TRIMESTER, ABOUT 10%. THE RISK ASSOCIATED WITH EXPOSURE OF AN UNIMMUNIZED PERSON TO AN INFECTIOUS RUBELLA SOURCE IN A HOSPITAL IS PROBABLY THE HIGHEST AND MOST RELIABLE PREDICTION THAT WE CAN MAKE CONCERNING PREGNANCY OUTCOME - SO THAT IT IS SURPRISING TO FIND THAT NEITHER SCREENING OF HEALTH PERSONNEL FOR IMMUNE STATUS (FOR RUBELLA) NOR PREVENTIVE IMMUNIZATION IS MANDATORY ACROSS THE UNITED STATES. ONLY SINCE 1978 (3 YEARS AGO) WHEN A MALE OBSTETRICAL RESIDENT WITH RUBELLA HIMSELF EXPOSED 200 PREGNANT PATIENTS, HAS THE CALIFORNIA DEPARTMENT OF HEALTH RECOMMENDED THAT ALL HEALTH CARE PERSONNEL IN THE STATE, LIKELY TO BE IN CONTACT WITH PREGNANT WOMEN, BE SCREENED

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FOR ANTIBODIES TO RUBELLA. THE HIGH TURNOVER RATE AMONG HOSPITAL PERSONNEL DEMANDS THAT SUCH A PROGRAM BE CONTINUOUS IN ITS IMPLEMENTATION. NEW YORK STATE REQUIRES SCREENING OF FEMALE HOSPITAL PERSONNEL ONLY. WHY IS THIS RISK, SO WELL UNDERSTOOD AND AGREED UPON BY SCIENTISTS, CONSIDERED TO BE SO MUCH MORE ACCEPTABLE THAN THE FAR LOWER RISK FROM A RADIATION ACCIDENT - IN A RADIOLOGY DEPARTMENT, OR A CHEMICAL CONTAMINANT EFFECT? IS IT BECAUSE IT HAS INFECTIOUS ORIGIN, BECAUSE IT IS TOTALLY PREVENTABLE, OR BECAUSE IT IS A HOSPITAL PROBLEM?

RADIATION AS A PHYSICAL PHENOMENON HAS LONG BEEN KNOWN BY DIRECT OBSERVATION TO HAVE AN ADVERSE IMPACT ON SPERMATOGENESIS AND THE INTEGRITY OF HUMAN SPERM - BOTH IN ITS IONIZING AND NON-IONIZING FORM. THE UNITED NATIONS SCIENTIFIC COMMITTEE ON THE EFFECTS OF ATOMIC RADIATION HAS SHOWN THAT THE RISK FOR INDUCTION OF GENE MUTATIONS AND CHROMOSOME ABERRATIONS LEADING TO CONGENITALLY MALFORMED LIVEBORNS, AND PRE-NATAL LOSS IS MARKEDLY HIGHER FOR THE PATERNAL CONTRIBUTION TO THE PREGNANCY WHEN COMPARED WITH THE MATERNAL CONTRIBUTION FOR THE SAME DOSE OF IONIZING RADIATION. WITHIN THE APPROPRIATELY MONITORED ENVIRONMENT OF A RADIATION FACILITY WHERE FILM BADGES ARE REGULARLY AND RELIABLY USED, AND HIGH QUALITY WORK PRACTICES MAINTAINED, THE PROCREATING MAN AND THE PREGNANT WOMAN AND HER EMBRYO/FETUS ARE KEPT WITHIN SAFE WORK LIMITS. THE POSSIBILITY OF ACCIDENTAL HIGH DOSE EXPOSURE WOULD INCREASE THE RISK OF DAMAGE TO THE RAPIDLY DIVIDING CELLS OF THE TESTES AND THE EMBRYO, IF PRESENT IN THE WORKPLACE. SHIELDING APPROPRIATE TO EACH SITUATION IS AVAILABLE.

THE EXAMPLES FOR CHEMICAL CONTAMINATION IN THE WORKPLACE COMPARE, IN PART, WITH IONIZING RADIATION. THE EXPERIENCE SO FAR HAS BEEN THE DIRECT OBSERVATIONS OF THE EXTREME IMPACT ON SPERMATOGENESIS OF DIBROMOCHLOROPROPANE (DBCP) AND KEPONE EXPOSURES. THE POTENTIAL FOR ADVERSE EFFECTS OF DAMAGED SPERM ON FEMALE REPRODUCTION HAS NOT YET BEEN ASSESSED. NOR CAN THE EFFECT ON THE HUMAN EMBRYO/FETUS BE EVALUATED FROM THE EXPERIENCE SO FAR.

THE CARCINOGENICITY OF A TOXIC SUBSTANCE USUALLY BECOMES THE OVERRIDING CONCERN FOR CONTROL OF THE WORK ENVIRONMENT, SO THAT THE CONCERN FOR REPRODUCTIVE INTEGRITY WOULD BE FOR THOSE COMPOUNDS WHICH HAVE BEEN FOUND NOT TO BE CARCINOGENIC. POTENTIAL ADVERSE EFFECTS ON THE REPRODUCTIVE SYSTEM OF MEN AND WOMEN WOULD STILL HAVE TO BE ASSESSED. IN THE CASE OF EXPOSURE TO ANESTHETIC GASES IN OPERATING ROOMS AND DENTAL OFFICES, THE EPIDEMIOLOGIC EVIDENCE INDICATED BOTH CARCINOGENIC AND REPRODUCTIVE EFFECTS AND GAS SCAVENGING CONTROLS ARE USUALLY NOW IN GENERAL USE, PROVIDING THE ADEQUATE PROTECTION FOR ALL WORKERS.

THERE IS ONE OTHER IMPORTANT FACET OF THE REPRODUCTIVE EFFECTS OF EXPOSURE TO TOXIC SUBSTANCES. IN 1978 THE DEPARTMENT OF LABOR PROPOSED RULES GOVERNING THE CONDITIONS OF EMPLOYMENT FOR 10- AND 11-YEAR-OLD WORKERS IN THE HAND-HARVESTING OF SHORT-TERM CROPS TO ENSURE THAT EXPOSURE TO PESTICIDES AND OTHER CHEMICALS WOULD NOT HAVE AN ADVERSE EFFECT ON THEIR HEALTH AND WELL-BEING. IT WAS VERY SOON DISCOVERED THAT IT IS IMPOSSIBLE TO MAKE SUCH AN EVALUATION ON THE BASIS OF CURRENT BIOLOGICAL INFORMATION OF THE EFFECTS OF TOXIC SUBSTANCES ON PRE-PUBERTAL CHILDREN. THE PERIOD OF RAPID GROWTH FOR THE OVARIES AND UTERUS OCCURS FROM

9 TO 13 YEARS, WITH A DOUBLING OF THE WEIGHT OF THE OVARIES AND MORE THAN TREBLING OF THE UTERUS WEIGHT. IN BOYS, THE RATE OF TESTES GROWTH BEGINS BEFORE 8 YEARS OF AGE, AND ENLARGEMENT OF THE GENITALIA IS PROGRESSING BY 10 YEARS OF AGE. UNIQUE DEVELOPMENTAL PROCESSES OCCUR IN TESTICULAR DEVELOPMENT PRIOR TO AND DURING PUBERTY. IT IS NOT KNOWN TODAY WHETHER SOME CONTAMINANTS COULD SPECIFICALLY AFFECT THE PRE-PUBERTAL MALE AND FEMALE DURING THIS CRITICAL PERIOD OF GROWTH. MORE DISCONCERTING IS THE REALIZATION THAT THERE IS VERY LITTLE RETRIEVABLE ANIMAL TOXICOLOGICAL DATA APPLICABLE TO THE IMMATURE INDIVIDUAL. IN THIS EXAMPLE, THERE IS A LARGE BLACK HOLE OF IGNORANCE - SO VAST INDEED THAT THE EXPOSURE OF PRE-PUBERTAL WORKERS TO PESTICIDES AND OTHER TOXIC SUBSTANCES SHOULD BE PROHIBITED UNTIL SUFFICIENT ADEQUATE DATA FOR STANDARD SETTING ARE AVAILABLE.

SO WHAT ARE THE ANSWERS TO YOUR QUESTIONS IN RELATION TO THE REPRODUCTIVE SYSTEM?

Q1. TESTS RELATING TO THE MALE REPRODUCTIVE SYSTEM ARE AVAILABLE THAT CAN BE PERFORMED WITH ACCURACY, BUT MANY OTHERS ARE STILL IN THE DEVELOPMENTAL PHASE. VITAL STATISTICS AND EPIDEMIOLOGIC STUDIES ARE NECESSARY FOR RELIABLE COMPARISON OF CHILD-BEARING POPULATIONS, AND IN SOME INSTANCES, ASSESSMENT OF INDIVIDUAL EXPERIENCE. EARLY PREGNANCY DIAGNOSIS IS NOW ACCURATE AND IMPROVES THE SENSITIVITY OF EPIDEMIOLOGIC STUDIES.

Q2. FOR THE MALE WITH A LOW SPERM COUNT, WE DO NOT KNOW IF HE IS MORE OR LESS SUSCEPTIBLE TO FURTHER DETERIORATION FROM BIOLOGICAL, CHEMICAL OR PHYSICAL INSULT.

ADVERSE EFFECTS ON THE EMBRYO/FETUS FROM HAZARDOUS EXPOSURES HAVE BEEN QUANTIFIED DIRECTLY FOR RUBELLA INFECTION (22% AND 10%), INDIRECTLY BY EXTRAPOLATION FROM HIGH DOSES AND ANIMAL OBSERVATIONS FOR IONIZING RADIATION (A FRACTION OF A PERCENT PER RAD), AND NOT AT ALL FOR TOXIC SUBSTANCES, ALTHOUGH EXPOSURE TO UNCONTROLLED ANESTHETIC GASES APPEARS TO SHOW A RELATIONSHIP TO ADVERSE PREGNANCY OUTCOME.

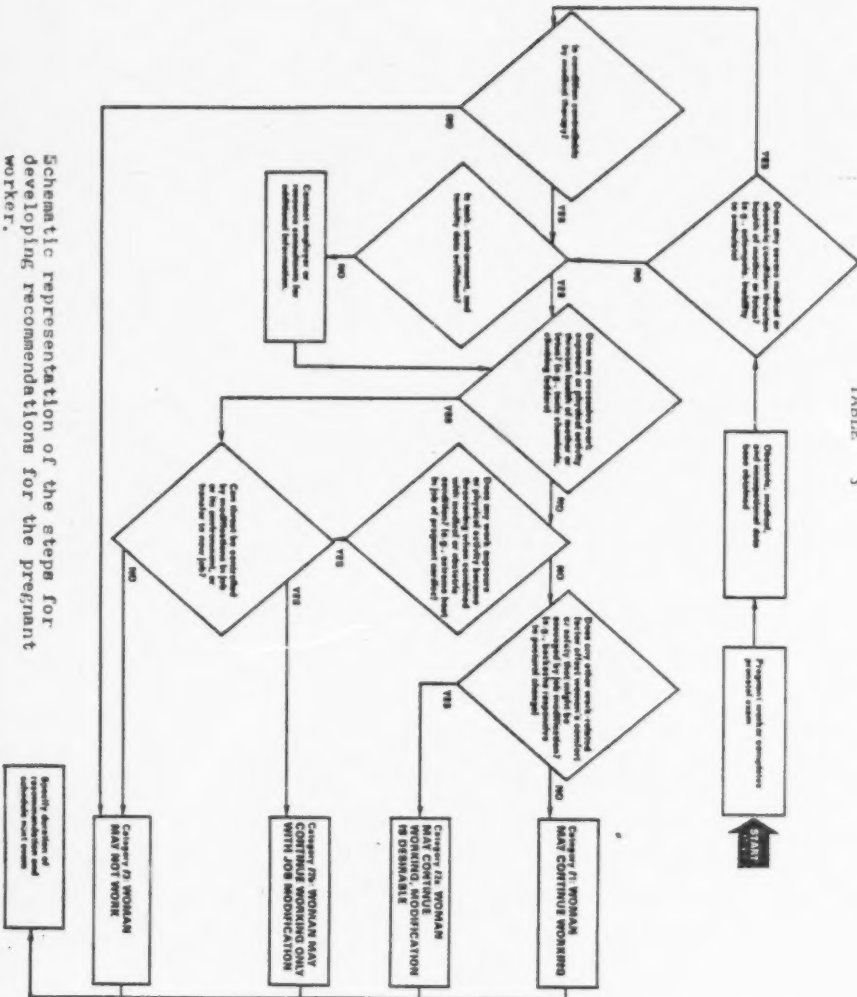
Q3. THE LEVEL OF PREDICTABILITY IS RELATED TO A QUANTIFIED RISK ASSESSMENT. ONE CHANCE IN 4 OR 5 OF ADVERSE PREGNANCY OUTCOMES FOLLOWING FIRST TRIMESTER RUBELLA INFECTION IS FAR MORE CERTAIN THAN 1 CHANCE IN 500 OR 1000 OR MORE FOR RADIATION EXPOSURE BEYOND THE SUGGESTED OCCUPATIONAL STANDARD. FOR TOXIC CHEMICAL EXPOSURE, E.G., DIOXIN - BASIC BIOLOGICAL DIFFERENCES BETWEEN EXPERIMENTAL ANIMALS AND HUMAN POPULATIONS PREVENT THE DEVELOPMENT OF A RELIABLE RISK ASSESSMENT - QUALITATIVELY OR QUANTITATIVELY.

IN 1977 NIOSH AND THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS DEVELOPED A DECISION CHART IN COLLABORATION WITH CLINICIANS, WORKERS, AND SCIENTISTS WHICH PROVIDES DIRECTION FOR ASSESSING CONDITIONS WHERE THE PREGNANT WOMAN MAY CONTINUE WORKING WHERE JOB MODIFICATION IS DESIRABLE, WHERE JOB MODIFICATION IS NECESSARY, AND WHERE THE WOMAN SHOULD NOT WORK. THE ALGORITHM

TAKES INTO ACCOUNT THE PREGNANT WOMAN'S CLINICAL CONDITION.
IN THIS SITUATION, THE WOMAN AND HER ATTENDING PHYSICIAN ASSESS
THE RELATIONSHIP OF HER WORK AND HER PREGNANCY.

I LEAVE QUESTIONS 4, 5, AND 6 TO THE OTHER PANELISTS HERE
TODAY.

TABLE 3



Schematic representation of the steps for developing recommendations for the pregnant worker.

I CONCLUDE WITH A COMMENT CONCERNING THE MOST RECENT AND EXTREME EXAMPLE OF WORKPLACE EXPOSURE FOR WOMEN - WOMEN WORKING IN THEIR HOMES IN NIAGERA FALLS - NEAR LOVE CANAL. AS A STUDY POPULATION, THEY DIFFERED VERY LITTLE IN TERMS OF EXPOSURE TO TOXIC SUBSTANCES, AGE AND PROCREATION EXPERIENCE - FROM ANY GROUP OF WOMEN AT WORK - IN A JEWELRY FACTORY IN PROVIDENCE, FOR EXAMPLE.

THE SCIENTIFIC AND MEDICAL SYSTEM COULD NOT PROVIDE ONE APPROPRIATE REPRODUCTIVE (OR ANY OTHER) END-POINT UPON WHICH THERE COULD BE AGREEMENT THAT IT WOULD HAVE SCIENTIFIC LEGITIMACY. TO THIS DAY, NOT ONE STUDY HAS BEEN CARRIED OUT THAT HAS MET THE FLUCTUATING ARRAY OF CRITERIA THAT IS SUPPOSED TO REPRESENT SCIENTIFIC ACCORD.

I WOULD SUBMIT TO YOU THIS COUNTRY'S SCIENTIFIC ESTABLISHMENT HAS HAD A MASSIVE RESEARCH BUDGET FOR THE PAST 20 YEARS. YET IT WAS UNABLE TO AGREE SUFFICIENTLY ON EVEN ONE SINGLE SOLITARY TEST APPROPRIATE FOR THE ASSESSMENT OF RISK TO THE HEALTH (INCLUDING REPRODUCTION) OF THAT WORKING POPULATION IN LOVE CANAL. LET US NOT HIDE OUR HEADS IN THE SAND AND EXCUSE OUR PARALYSIS WITH THE EXTERNALITIES OF THE SOCIAL CRISIS BLINDING THE SCIENTIFIC LEGITIMACY OF TESTS. LET US ADMIT THE REALITY THAT OUR SCIENTIFIC/ MEDICAL SYSTEM DOES NOT EVEN NOW HAVE A TEST OR STUDY DESIGN WHICH CAN BE AGREED UPON THAT WILL PROVIDE THE ANSWERS YOU ARE SEARCHING FOR TODAY, WHETHER YOU ARE CONCERNED WITH HAZARDS IN THE WORKPLACE OR THE ENVIRONMENT.

IF THE LITERATURE WE TURN TO IS REplete WITH POTENTIAL TESTS AND STUDY DESIGNS WAITING FOR VALIDATION - A CRITICAL CRITERION FOR GETTING OVER THE HURDLE OF CREDIBILITY - WHO IS GOING TO SUPPORT THE VALIDATION PROCESS? WHEN APPLIED DIRECTLY TO HUMAN POPULATIONS, IT INVOLVES EXPENSIVE EPIDEMIOLOGIC METHODS.

THE NATIONAL INSTITUTES OF HEALTH ARE THERE TO DO THE BASIC RESEARCH AND TO DEVELOP TESTS. CURRENTLY I SEE NO VISIBLE MEANS OF SUPPORT IN THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OR THE ENVIRONMENTAL PROTECTION AGENCY FOR GETTING US OVER THAT HURDLE OF VALIDATION.

NEXT TIME - IN THE WORKPLACE OR THE ENVIRONMENT AT LARGE - WILL WE BE PARALYZED AGAIN OR WILL THE CRITERIA FOR SCIENTIFIC LEGITIMACY CHANGE?

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Mr. GORE. Thank you very much.

I recognize the difficulty of these issues and I appreciate your sensitivity to them.

Dr. Stellman, we are particularly pleased to have you with us during a time of some trouble and recognizing that some of your thoughts are elsewhere, we are particularly grateful for your willingness to come and help us with these issues because we did not think we could do it without your presence here.

We thank you for being here and invite you to proceed.

Dr. STELLMAN. I have to apologize for no written testimony. It has been impossible to do it.

I would like to make an attempt at joining the women's issue with the broader issue of the theories of susceptible workers and even to broaden it out a bit from the question of genetics and to talk about what I see as the coming trend and that is consideration of the workers as the susceptible worker.

I believe the women's issue places the reasoning that is behind the susceptible worker theories in as clear a context as we can hope to have. As you yourself pointed out, we wear our X and Y chromosomes on our sleeve and it becomes a more easy matter to understand the reasoning behind these policies.

The assumption that it is legitimate to exclude women from certain workplaces is based on several generalizations that I think it pays to take a few minutes to review.

The first is, as Joan Bertin pointed out, is the assumption women are permanently pregnant until proven otherwise and the fact that one is fertile places one in the at-risk category.

In fact, pregnancies in the United States are planned. You have three fertile women sitting in front of you, none of whom is pregnant and none of whom plans to be. In fact, the current population study surveys in June 1977 place child-bearing expectations of women between the ages of 30 to 39, who are in blue-collar socioeconomic status, as approximately 1 percent.

In fact, the major unplanned pregnancies in our society are among teenage girls, not among women, and they are not the people whom we are discussing.

What does this show, this generalization about all fertile women being permanently pregnant as a class? It shows the application to a broad population of a narrow theory. I think that is the first principle of the susceptible worker that the case of women represents.

Also, when we target in on women as a class, we are particularly forgetting about men and I don't assume it is news in the Halls of Congress that it takes a male and a female to reproduce.

Unfortunately, the policies of exclusion of women remove the responsibility for paternity from the males and, in fact, overlook the burden of science which shows that the males are indeed vulnerable, as Velma has pointed out.

I almost look at our scientific beliefs as a direct reflection on social beliefs in which sperm are cast into the aura of being invulnerable and, in fact, we anthropomorphize the entire reproductive process when we picture poor helpless female ova waiting to be fertilized by the most strong and the most masculine of the sperm and that is the comment theory that applies in almost all reproduc-

tive texts in which it says only the strongest of the sperm can make it to the position of fertilizing the ova.

This is ridiculous. First, I think it pays to realize some of those sperm are little girl sperm because, in fact, it is the male who determines the sex, so half of them are female and half of them are male.

This kind of anthromorphization of the whole process has pushed its way not only into employment practices, but into the biology we teach our medical students and scientists.

We know it is not true. We know that, in fact, ionizing radiation has a greater effect on the male than on the female and we know weakened sperm can indeed fertilize ova and result in stunted growths or birth defects or infertility.

We know cigarette smoke affects males. We know now that appropriate genetic testing is available that Down's syndrome, which had previously been attributed to tired, old ovaries, is one-third attributable to paternity.

So exclusion of women is attacking only a part of the problem if reproductive health is really the issue at question. If reproductive health is really the basis of the screening out of women workers who are fertile, then we are only attacking a very small part of the problem and I think an examination of some of the chemicals that have been the basis of this screening process is very useful for illustrating this.

I would like to focus on one in particular and that is methotrexate. We have both spoken about people in the health care industry, which is the largest employer in the United States today and major industry in the United States today and methotrexate is a very commonly used chemotherapeutic agent for the treatment of cancer patients and women have been banned, excluded from the production of methotrexate.

Now, the qualities of chemotherapeutic agents are they have a profound effect on the cellular biology, in particular the genes and the DNA and chromosomes.

There is no evidence at all to assume that the males are not affected by methotrexate. Yet, it is the females who are excluded.

There clearly is an effect of methotrexate during pregnancy but for the nonpregnant worker, there is no evidence at all that one sex would be more affected than the other.

Yet, women have, by employment policy by a large company, been excluded from the manufacture of methotrexate. This illustrates to me very profoundly the whole application of the susceptibility theories to the selectivity of choosing who you are going to target and when, and not only are males and nonfertile females not allowed to remain in the manufacture of methotrexate, but females are the people who deliver the methotrexate to the patients on the floors, and there have been five studies on the effect of chemotherapeutics on the nurses who deliver these.

They have shown genetic changes of mutagens in the urine, so this, to me, is a quintessential example of how one chooses one's tests when it is economically and socially warranted.

One can easily exclude women from a manufacturing process, but one cannot exclude women from nursing. We would have to

shut down the health care system. The selectivity of the target group is, to me, a major danger of all susceptibility theories.

It is right in line with the history of the protectionism of the woman worker. From the outset, protective legislation has always protected women out of the good jobs and left them unprotected in the areas where they needed the protection most.

In California State, protective legislation always excluded women from overtime during the canning season. Weight-lifting laws have never applied to waitresses or nurses. Hours of work have never applied—night work laws have never applied to those areas where women were required to work at night for the good of the industry, so the selectivity of protection is another very key target that one must examine in dealing with all susceptibility theories.

I propose that most of them miss the preponderance of risk that workers take in simply seeking to eliminate the risks of having a worker around that one might have to protect for or having to put some extra money into a process to afford the best protection for all.

If we turn to the area of genetics and leave the issue of fertile versus nonfertile, the medical basis of selection of workers is more difficult to understand and it is not clear to me the extent to which any particular test is used at present in industry.

It is not clear to me which companies are doing what to whom. What is clear to me, rather than the debate over a G-6-PD or antitrypsin is that the trend is there.

The American Occupational Medicine Association, in its Denver meeting several years ago, devoted its entire meeting to the susceptible worker.

I see Velma is chairing a session at a major conference sponsored by the American Council of Government Industrial Hygienists in Arizona Occupational Center of Safety and Health on the susceptible worker.

This is to me a frightening portend of where we are going.

Last month's Journal of Occupational Medicine ran an article and article response on employment and preemployment screening.

It is very unusual for that journal to write an article and an article response, to publish it in that way. It is the major area of debate.

Several months ago, the American Industrial Hygiene Association published an article by a company in Wyandotte, Mich., which they explicitly laid out their methods for screening out susceptible workers.

I understand from talking with the company, more than 100 other companies have sent for reprints. It is not clear what the extent of the testing is and certainly the company responses will be different.

It is not a monolithic industrial world. Some companies are far more responsible than others. I think the trend is one that must be examined very closely.

I took the time to just pull out—I am not going to read through all these papers—but I took the time to pull out a few papers on alpha-1-antitrypsin which is an enzyme marker that is thought to be related to the predisposition for development of bronchitis and on the pulmonary diseases.

In the early 1970's, several studies were carried on on coke oven workers, which is an egregious thing to do and deserves comment because if there is one occupation in which everyone will agree workers are at extreme risk, it is working in a coke oven and there is no argument on any side of the issue that coke ovens represent cancer risks and chronic bronchitis risk and that is well known and agreed upon.

Yet, in the early 1970's, papers started appearing that were based on surveys conducted to assess the contribution of cigarette smoking, occupational and genetic factors in the development of industrial bronchitis. The Mittman group, in particular, in California, did several studies and are still doing studies on looking at particular susceptibilities.

They say that work, smoking, and family history accounted for 40 percent of the variability in the severity of symptoms among men with chronic bronchitis.

That leaves 60 percent unaccounted for and these findings suggest that the work group is composed of men with a range of susceptibility to development of bronchitis.

At least part of this variability is genetically determined. If susceptible subjects can be identified during preemployment screening and are effectively excluded from hazardous occupations, some case of chronic bronchitis may be prevented.

I would like to call your attention to the data itself in which the genetic screening tests were found not to be strictly significant and where, in fact, it was work and large amounts of cigarette smoking that accounted for almost all of the identifiable disease.

The emphasis on family history is another one that must be approached extremely carefully. Virtually every one of our OSHA standards, of the few that exist, calls for a medical screening that includes the family history.

It does not take a sociologist to know that the parents of coke oven workers were probably not surgeons and corporate executives, but were probably coke oven workers or similar people themselves.

Family history, which do not take into account the exposures of the family, will lead us down another primrose path of dalliance toward selecting out workers on a prejudicial basis based on their socioeconomic status.

We have to find out who people's parents are and what they did if we are going to include them in the occupational history. I pulled out three very recent papers on alpha-1-antitrypsin, one on elastic recoil in the lungs, which is related to the development of chronic obstructive disease, and they clearly find that there is no relationship.

It is concluded that in a major working population, evidence of diminished pulmonary elastic recoil is not a function of AAT concentration. In Yugoslavia, 3,000 men in an industrial and mining center were screened specifically and out of that, 26 men were found to have the phenotype and the bulk of the work precludes—while there is a very high incident of chronic obstructive pulmonary disease in this town, the low prevalence of the pi Z gene, it does not appear to account for much of the high rate of chronic obstructive pulmonary disease found in this population.

A similar community study of the relation of alpha-1-antitrypsin levels to obstructive lung disease in Arizona found that the data "militate strongly against the use of any quantitative determination of alpha-1-antitrypsin as a test to identify subjects with moderate deficiency for the purpose of predicting later development of chronic respiratory disorders."

I point these out because they are indirect contrast to what continues to be published in the peer review literature where, without any hesitation, quotes such as by a group at Johns Hopkins the association between very low concentrations of serum alpha-1-antitrypsin and the development of pulmonary emphysema has been well-documented through epidemiologic, clinical, and laboratory investigations.

The list of such references is continual and, in fact, the articles that have been published on preemployment placement rely heavily on this background work.

Reliance on these studies, which make their way into the literature, can lead us into the development of policies which are grossly contrary to the public health history of our country and to the, I think, the law of our country.

I think I would like to just turn the argument to the whole public health prospective since I am now an associate professor of public health and to ask several questions that are very much related to the questions that you have raised.

First, the hallmark of a screening test of any selection process depends on the test, A, being specific, and B, having high degree of efficacy in detecting the event that it is looking for.

There is no evidence at all that these tests are predictive, just as fertility is not predictive of child-bearing.

These tests do not protect all workers. Their level of detection is very poor; just as selecting and excluding fertile women leaves unprotected the men and the nonfertile women left on the job.

If we turn aside from the discussion of how much variability you can explain, I think the most important thing to look at in the whole emphasis of the susceptible worker is to understand that it turns public health policy on its head.

If we look at infectious disease as the clearest example of how science and public health has approached a disease process, we can see clearly how public health is turned on its head.

Infectious disease is based on an agent infecting a host, resulting in a disease and at no time has there ever been a concentration on the host and I just pulled out of the literature the actual incidences of both measles and polio, to which we in the United States have devoted a great deal of effort in eradicating.

In 1950, there were only 33,000 cases of polio in the United States. That, in terms of the population in the United States, is not a huge number of cases. Yet, we unstintingly went ahead and poured millions of dollars and a great deal of thought and effort into polio.

Certainly as a child who grew up before the vaccine was available, I am clearly in favor of eliminating this great fear that parents had for their children. Yet 33,000 people in the context of our society is not a great deal of people and at no time was there an effort made to say, what made those 33,000 people different so that

they were susceptible to polio, whereas the other millions of children did not get it.

I don't believe that argument was aired a single time during the entire fight against polio.

Similarly, with measles, a great deal of effort has gone into eradicating measles. It is still a major thrust of the Center for Disease Control. I am sure most of us have had measles and realized we spent a miserable week. It was not the world's worst event, but we always hear about the complications of measles.

In fact, in measles, the death-to-case ratio represented 0.9 per 1,000 cases reported and encephalitis, a major fear from measles was 1.4 cases per 1,000 cases of measles reported in 1973, so that, again, when we talk about the complications of this childhood disease, we are talking about a miniscule number of people who would contract those complications, yet never once has the argument been raised, how do we find those people and select them out.

The approach has been to eliminate the agent and not to concentrate on the host. We in the 1980's have turned our concentration on the host.

We have turned it on the host in other questions of lifestyles. We are turning it on the host in the questions of cancer in the workplace and we are clearly turning it on the host in the question of susceptible workers.

The fact is we can't turn to the host, because we don't understand the process. I think vinyl chloride is a very good example. We know that vinyl chloride causes liver cancer in some of the people who are heavily exposed.

Other cancers are probably also induced. There are several proportionate mortality studies which show an increased rate.

We don't understand the mechanisms. We don't even know all the risks that are involved.

Most of this is just simply based on shaky science and I am afraid that the emphasis of the susceptible worker is a manifestation of social policy and not of science.

I must reiterate and reemphasize what Joan Bertin said. We are not talking about something that is a choice. We are talking about the law of the United States which says that a workplace free from recognizable hazard shall be provided to every man and woman in the United States.

And I think we are talking about the basic moral fiber of the United States, where we are talking about freedom and justice for all, not just the genetically suitable.

I think I might like to end on a personal note. I think I am particularly sensitive and susceptible to these issues myself. I am the child of a survivor of the Holocaust and was born in a displaced persons' camp and we, as a family, and many millions of others, suffered very directly and convincingly the results of policies based on dubious genetic traits.

While I don't see gas ovens being built and constructed in the United States, I do see that many of the premises which led to that terrible time are again beginning to surface here and I think that given the light of day, the American people will not tolerate that.

I thank you for the opportunity for bringing this to the light of day. Thank you.

Mr. GORE. Thank you for a very powerful statement. You are an interesting panel; very compelling testimony from all three of you.

I hardly know where to start with the questions. Dr. Hunt, let me begin with you.

Your statement enhanced my appreciation of the flaws in the research and the difficulties in relying on some of these methods that are under discussion.

What research priorities would you recommend to clarify this matter?

Dr. HUNT. I think the process of research basically goes through the stages of basic research, use of that information for test development and once we have tests that are available, which is the stage I say we are at now, we need validation of those tests.

The validation process invariably involves dealing with human populations, testing it on human populations. It is very expensive.

However, in terms of, again, the therapeutic area and some of the issues relating to infectious disease epidemiology, we have been very successful in going through that phase of field testing vaccines, of insuring that there is a valid expectation that good will come from the development of the agent and the basic research that was fundamental to it.

We are not seeing the logical flow of these three factors: basic research, test development, and validation.

I would say that the agencies that should be dealing with studies that would validate the tests to eliminate or reduce the controversy concerning their applicability are just going to have to be very consistently funded to do that.

I would say that the usual role of the National Institutes of Health has been to do the basic research and the responsibility to deal with the development of tests has been within the Center for Disease Control and the Environmental Protection Agency.

They have had more of the mission of both developing tests and validating them. However, what I have seen from my experience is that when it comes to the maintaining of an appropriation that will insure the validation of tests, we are not seeing that today. I would say we are at almost a crisis point if we have spent the billions that we have spent on basic research, some of that on test development, and now we cannot make that last effort to validate the findings.

But if somebody can provide me with a test that has been to the satisfaction of the scientific community and those with whom they have to deal, be it legislators, the public, the legal profession, or whatever, that they are satisfied with its underlying scientific reliability and its validation, I would sure like to know which one it is.

It may exist, and I have not come across it yet, but you invariably get all the arguments as to why a certain test should not be used and validation is going to be the key point and the appropriations for that are disappearing.

Mr. GORE. Those comments are well taken.

In listening to your testimony, the testimony of the panel, I noticed an unexpected bridge between yesterday's testimony and today's.

Yesterday, we focused in part on the predictive nature of some of the tests that are used and here the same issue arose. Two of our

panelists mentioned it; that is, the selection of fertile women as an indicator of damage to the fetus has a high number of false positives in the language of Dr. Rocky, one of our witnesses yesterday, and a large number of people are excluded from employment opportunities on the false assumption that the genetic market is accurately predicting damage that the employer is seeking to avoid.

That issue seems to be one of the dominant ones in this whole area and for the first time, I think that we may consider recommending legislation to require some sort of minimum standard for predictability before a test can be used for anything other than advice.

The same question applies to false negatives. The use of that genetic marker, looking for fertile females, excludes a number of men who would also be carriers of genetic damage to the offspring.

Ms. Bertin, I found myself in slight disagreement with one of your statements and I wanted to explore it with you.

You used at one point the words "the same" in discussing the potential damage to the fetus or to the offspring would be the same with men being exposed as with women being exposed.

It occurs to me that there are two separate situations that have to be discussed. One, before pregnancy, and after pregnancy, and it seems rational to conclude that in most cases, the degree of risk to the offspring is likely to be greater from exposure across the placental barrier than exposure through the sperm or the ovum.

Ms. BERTIN. I don't believe that is a rational conclusion. Let me give you an example and I will at whatever relevant point defer to my scientific colleagues, because I am now going to be repeating to you information I have received from some scientific experts.

The example of radiation has been given. Radiation may cause genetic damage. The likelihood of genetic damage being caused to a male is greater than genetic damage being caused to a female by preconception exposure, because of the rapidly dividing cells that Dr. Hunt described earlier.

Therefore, if you have a man and a woman who are exposed to X-rays and they are both planning to have a child in the next month, the man is more likely to pass on some damage to the future child than the woman.

There may be a more comparable situation between the preconception exposure of the man and the postconception exposure of the pregnant woman.

That would be where the analogy would be, but simply because you have the visual impact of the pregnant woman does not mean that the fetus is necessarily more vulnerable because you can see it.

The process is going on in a variety of different ways and I believe that Dr. Hunt was trying to describe that and Dr. Stellman also is describing that.

Lead is another example. OSHA conducted extensive hearings in formulating the lead standard. The lead standard has been the subject of tremendous controversy.

It has recently been upheld by the District of Columbia Court of Appeals and certiorari has been denied by the Supreme Court. So the standard at this moment has been upheld as lawful.

In that standard, OSHA concluded there was no reason for assuming that pregnant women were at greater risk than were men. The greatest known reproductive hazard from lead exposure is the preconception hazard to the sperm and the ova and a similar effect occurs with regard to both men and women.

Now, we know that lead crosses the placenta, but we don't know what it does when it gets there. There are few, if any, valid studies indicating any actual mechanism for injury which occurs by virtue of that transplacental effect.

What we do know is that there is a significant preconception effect and that the effect is the same for both men and women.

One of the points I was trying to make is that I believe we are all afflicted with the stereotype that the fetus, the pregnant woman, is more susceptible.

I think we have to look beyond that stereotype and test that stereotype, because in many of the instances we know about, it is not true.

Let me just make one more point while I am talking about this. The rubella example was given earlier and, of course, it is true that pregnant women are particularly susceptible. But what about the man who catches rubella at work in the hospital and brings it home to his pregnant wife? The effect is the same and it seems to me if what we are talking about is the effect, then we have got to address that effect, no matter how it occurs.

Mr. GORE. I think where you have an infectious agent or a particularly virulent chemical toxant like dioxane, then you have to worry about the exposed individual taking the agent in question along with them on their clothing or whatever.

I am willing to believe that there are cases where damage to the sperm resulting in damage to the offspring might be greater than damage to the fetus across the placental barrier.

I guess I still am concerned that we have a clear vision of what is involved here. I don't have any problem seeing that in the case where the pathway of harm is through the parent prior to conception—I don't have any problem seeing that the damage to the offspring may be equal whether the pathway is through the father or through the mother.

A couple of years ago, I had a heated argument with the chief medical officer of the Veterans' Administration on the agent orange question, who argued before a hearing I chaired that that damage could only travel by way of the mother.

Of course, a few thousand years ago, people believed that only the mother played a role in conception but subsequent discoveries proved that hypothesis to be inaccurate.

Now, I believe that this is probably equal with variation, according to particular substances, of course, and there will be examples where the pathway through the male, as you mentioned, will be greater.

I would not be surprised, however, if it was the exception rather than the rule that damage, by way of the parents prior to conception, was not less than damage directly across the placental barrier.

It may be rational to look at that hazard if you have an accurate genetic marker or accurate predictor that may, in fact, be a greater risk.

Ms. BERTIN. I disagree strongly with that proposition. I think it is just that attitude that has resulted in the problem we are facing today, which is that all of the research has been directed at women and that there has been a woeful lack of attention paid to the male contribution. Just the other day, I read in the New York Times, the Center for Disease Control publicly acknowledged there have been virtually no studies done on male reproduction and they were about to sponsor some, because current information suggests that this is an area that had been very badly disregarded to the detriment of everyone.

If we are talking about alteration of the genes, mutagens are not gender-specific. They don't pick out a woman and only harm her genes. They get all of us.

And if we are in a workplace where there are carcinogens and mutagens, they are going to hit everybody.

Mr. GORE. Dr. Stellman.

Dr. STELLMAN. I disagree with both of you.

Mr. GORE. Can I ask you to hold your response. We have a vote on the floor and it won't take more than 8 or 9 minutes and we will recess briefly.

[Recess.]

Mr. GORE. This subcommittee will come back to order.

When we recessed for the vote, we were about to hear from you, Dr. Stellman. I am looking for some help on this issue.

Perhaps my question as originally phrased reflects an inaccurate preconception. If so, I want some help in clarifying it.

Dr. STELLMAN. I think one of these problems is there is a fundamental lack of data on which are more important, preconception events or postconception events.

It is unquestionably clear that things that affect both the genes and the chromosomes can have a profound effect on the outcome of a pregnancy or the ability to produce a viable pregnancy and that, in addition, the health of the sperm or the ova, besides the chromosomal effect, can also be profoundly affected preconceptually.

Whether this is 50 percent, 60 percent, 30 percent of the total burden that we have of adverse reproductive outcomes is a very debatable issue.

The estimates on spontaneous abortions, miscarriages, range from 10 percent to 96. You see the whole range in the literature. So I think that is not an important argument.

Likewise, I think that Joan was sort of cornered into arguing over the extent of the effect of toxic substances on pregnancy.

First, there is no placenta during the first trimester that functions. So to talk about transplacental passage does not have meaning during the first trimester and the level of toxic substances that will enter the embryo will vary with stage of pregnancy and that again is a very, very limited data base.

I don't quite think it is a relevant argument. And I don't think that Joan Bertin wants to argue for pregnant women to be exposed to toxic substances, because they will undoubtedly be at risk from

certain substances and we are the only industrialized nation in the world without any decent paternity policy for women.

In the lead standard and the other things we have been arguing against the exclusion of women, I have always felt that what we have achieved is an equal right to be poisoned. I cannot push for allowing pregnant women to remain in the toxic work place.

On the other hand, I can also not generalize that the fact that one is pregnant, ipso facto, means there will be an adverse outcome. The relative weights and contribution of all this is not known.

The safest and surest thing to do would be to allow both future mothers and future fathers to have a prepregnancy planning time when they could avoid exposure to toxic substances and when they are pregnant, I don't see any reason why we, as a society, could not provide medical retention plans to allow them not to be exposed.

Mr. GORE. How long prior to a planned pregnancy would that period be?

Dr. STELLMAN. I think that depends on the substance. If it is a dibromochloropropane worker, it would be a very long time before prepregnancy for the male to plan that.

A 3-month cycle for spermatogenesis; 72 days. It is not clear how susceptible the ova are to different substances.

None of this work has been done. Some of the biomedical tests that Dr. Karrh alludes to in his testimony might be appropriate to determine the levels of chemicals that are present in a person's body prior to conception. I think it is a fruitless argument to engage in, which is the greatest. They are all potential risk factors and they must all be addressed if we are to provide for good reproductive health in our society.

Mr. GORE. Given the uncertainties are enormous, you would agree that the magnitude of the risk to the fetus and the magnitude of the risk to the offspring through the parent prior to conception are comparable.

Dr. STELLMAN. I think you can't generalize. I think it depends on the substance. For ionizing radiation, preconception is greater than in utero. There was just a study that came out to show that.

In animals, preconception exposure, particularly in the male, is of greater import. For heavy metals, it will depend on transport properties. For things like diethylstilbestrol or thalidamide—the thalidamide was only effective as a teratogen between the 19th and 35th day of pregnancy. Otherwise, it had no effect at all.

Pregnancy and reproduction is a dynamic process that can't be generalized about in that way. You are focusing on the host rather than the agency again, and that is where the problems arise.

Mr. GORE. Yesterday we heard about the use of pre-employment back X-rays in the railroad industry as part of an effort to find back problems that might enhance the risk of occupational injury.

Dr. STELLMAN. You should look into the reproductive health after all those back X-rays.

Mr. GORE. That, by coincidence, was going to be my question. What would the hazards to men and their future offspring be from such X-rays?

Dr. HUNT. I think relating this question to the last one, the real usefulness of ionizing radiation to scientists is that it is a hazard

which can be much better controlled in terms of observations of its effect than we can do with toxic substances, so it is indeed the model that we have which we can pin some of the comparisons between preconception for men and for women and the subsequent effect on the embryo, fetus.

We can't do this with anything else very much. Ionizing radiation, both from animals and from human observations, is for the same dose showing very, very much more marked effect on the male than it is on the female and also on the embryo fetus.

We are talking about fairly low doses and I must admit we have that as suggestive information but when you extrapolate from high doses, that statistical result that you get is a very specific number of cases of spontaneous abortion, of congenital anomalies that could be expected because of preconception exposure to the female.

That is, the impact on the ovum is so miniscule that it ends up in the charts, which are being developed by the United Nations Committee on Effects of Ionizing Radiation.

As little question marks for the female, because we will not accept in the radiation field that there is no damage from radiation.

There is a basic underlying philosophy that any dose presents a risk of some damage, however low. But that question mark acknowledges that if such a low risk is involved for the preconception female that you can only just put a question mark and not any specific numbers.

Then, when we come to the issue of the embryo fetus, most certainly in the dose range that we tend to be speaking of in a controlled situation, be it a well-monitored working environment in a reactor, well-monitored working environment in industry with X-ray diffraction equipment, other methods or in a hospital, we do not have epidemiologically any case that I can think of, any case that we can absolutely attribute to an adverse effect on the child in terms of a congenital anomaly. We are talking about less than 5 rad per year to the mother and usually it is very much lower than in the work setting.

So that is the only complete set of data that is comparing those three situations of biological, chemical, and physical hazards that you are interested in and it seems to me, that we must get comparable information on, the body burden of pesticides; for example, in either a work population or in the environment at large, and run through that same relationship. The Atomic Energy Commission poured millions of dollars into their studies through the late 1950's and early 1960's. We are still standing on that base to develop our assessment of the relative importance of these three kinds of hazards.

We have it only for ionizing radiation. We have very little for any other environmental hazard.

Dr. STELLMAN. I think I would like to point out that the EPA recently proposed regulations on ionizing radiation in which they assumed that male risk and whole-body risk for radiation were equivalent and were seeking to set up special rules for the fetus in the workplace.

It is just again a presumption based on no excess male risk, so here we have a new regulation being proposed by the Government in this very area, if in the only area we have data, too.

Dr. HUNT. The only area we have fix on data, is on the reproduction of the whale.

Mr. GORE. In summary, then, all three of you believe that given the current state of knowledge, it is irrational to assume or conclude that the risk to the fetus directly through exposure to the pregnant woman is greater than the risk to the fetus through exposure to either parent prior to pregnancy; that such an assumption is currently irrational.

Dr. HUNT. Yes.

Dr. STELLMAN. I don't agree with that.

Dr. HUNT. You want to caveat that?

Dr. STELLMAN. The only thing I agree to is that we are talking about an extremely dynamic process and that that is the trouble with the whole field of reproductive toxicology; people have tried to make generalizations, none of which are true.

We have policies based on placental transfer, in the first 3 months, when all the organs are being formed, placental transfer is irrelevant before the placenta is not fully functioning.

Mr. GORE. Isn't there some comparable avenue of exposure from the mother to the developing fetus during the first 3 months?

Dr. STELLMAN. No.

Mr. GORE. Do they not share the same bloodstream?

Dr. STELLMAN. To some extent they do. In the very earliest part, it is what is called histiotrophic nutrition and the embryo draws its nutrition from stored blood. That is what menstruation is, the shedding of stored food supplies.

There is not a dynamic process of transfer between the maternal and embryonic bloodstreams at the outset of pregnancy. In fact, studies on cadmium transfer in rabbits, for example, have shown that the amount of cadmium that is transferred from the mother's blood to the rabbit is a function of the age of the embryo or the fetus and not how much is in the mother's blood.

We have gone full circle in imagery of reproduction. I also disagree, it used to be women were not considered part of the conception process. There was a model called the homunculus man in which it was felt that the fully formed offspring was actually contained in the male sperm and the mother simply served as a vessel.

Then we went to, along with the Victorian era, in which women were with the guardians of the home and art to imagery in which the placenta and the womb was the all-embracing "Garden of Eden" environment for the child and which, until thalidomide, was called the placental barrier.

It wasn't until the 1960's, after the thalidomide tragedy that the whole field of reproductive toxicology, teratology was born and we have now come to a model in which the placenta performs no function at all, in which the womb is simply a sieve, in which everything in the outside world is passed to the embryo or to the fetus. None of these models is correct. The mother and the womb do serve as a protective function; in fact, if you take a child whose father is a leadworker, that child probably stands a better chance of being less exposed to lead, who works in a dirty place, brings the lead home, but probably have less lead exposure in utero than after

being born because it is very well-documented that children of smelterworkers have high lead.

The mother protects the child from that. So all of these models are really mirrors of our social imagery of the role of the female.

They can't be generalized like that.

Dr. HUNT. I wonder if the caption of your summary might better include a probability concept in it, that it is not so much the fact that one avenue is greater or less than another, as it is that the probability of an effect is quite wide in all three instances of physical, chemical, and biological hazards.

But I would almost say that the probability of effect on the male for a given dose is going to be much higher, much narrower probability band than is the case for the same dose for the fetus; that indeed the fetus still can be damaged and that damage might turn out to be quite severe, but the variation, that variation band is going to be very, very widespread for that fetus.

It is far less likely to be affected for the same dose when compared with what might happen to the sperm along the way.

Mr. GORE. OK, I guess the root of my assumption was the belief that the process of development the fetus has under way carries with it a vulnerability that exceeds the vulnerability of the antecedent sperm and ovum.

Dr. HUNT. Yes; I don't think we can always say that.

Mr. GORE. I began the questions for this panel with questions of you, Dr. Hunt, on research priorities. Coming back to that briefly, in light of the discussion that we have just had, how would you characterize the current allocation of research effort as between preconception hazards and postconception hazards?

Dr. HUNT. I would say that the few studies that are being done on preconception are being done by the National Institute of Occupational Safety and Health for the male. That is about the sole location, I think, of studies in this area: The basic research being done in the National Institute for Child Health and Human Development has been primarily emphasizing the female preconception, the whole area of oocyte toxicity.

There are just very few people involved in both and not a large budget.

The second component which is more the area of developing tests and validating those tests, I see only in the area of a few epidemiologic studies, again by the National Institute of Occupational Safety and Health, in workplace epidemiology: The effort for test development is going along at a much faster pace in EPA now than it was a few years ago.

But, again, I suspect that the availability of funds for this very expensive component of validation which means human studies, we are going to have to rely perhaps on the Europeans and others to do this.

Mr. GORE. But the Science and Technology Committee is having hearings shortly on the research and development funds at EPA and what I regard as a mindless elimination of R. & D. effort.

But that is a matter of some controversy.

Dr. HUNT. I think it is the critical component of who is going to be responsible for validation; and whatever happens, who will do it and see that it is done.

Mr. GORE. Yes; another conclusion which I gathered from this panel's testimony was that the current examples of genetic screening or screening of people supposed to have enhanced risk in the workplace don't really reflect a rational, comprehensive view of what the most avoidable hazards really are, where we can really have the best effect on outcomes but exhibit instead an apparently irrational pattern that reflect other factors at work in addition to a legitimate concern for protecting the health of workers.

We had a very candid statement yesterday from representatives of the railroad industry about the impact of a particular statute that imposes a strict negligence standard on preemployment screening efforts, that leads to an irrational outcome, in my view, if you carry the outcome to what you would get if you sat down and said, "What are the worst risks and how can we avoid them?"

And you have cited several examples of risks that are arguably much greater than the risks that we now selectively try to avoid and argue for more and more reasoned, rational approaches to screening if we are going to have such screening.

Any of you wish to comment on that? Is that a fair summary of that particular point?

Dr. HUNT. Yes.

Ms. BERTIN. Let me just make one comment here. I think the lack of rationality is very troublesome because it suggests that other motives are at play in creating some of these policies.

I did want to clarify something because of a comment Jeanne made. None of us is arguing that real risks should be ignored. What we are arguing is that everyone should be protected. In particular real people require the same level of care and attention as those potential future children of some workers who may not intend to have any future children.

We are not trying to say that people should be equally poisoned. We are trying to say that if an industry is using toxins or producing toxins, look at all of the effects and start attacking the worst ones.

First, do it in a nondiscriminatory fashion, don't do it because of assumptions that you have about homunculus man or earth-mother or whatever, but based on some sort of a rational scientific approach.

Dr. STELLMAN. I think the model that should be looked at, I am very much concerned at the Cancer Center at Columbia, with early detection and screening for cancer itself, not of any necessity origin.

And there, even when looking for early signs of a frank disease, the ability to detect, to detect a significant number of those who are at risk are very limited. In fact, even the very popular ones that are tested that are out there are of limited usefulness.

Perhaps it is a good example for the Congress to bear in mind, the recent reexamination of tests that the American Cancer Society went through. They have just changed their recommendation for cervical pap smears from annually to every 3 years.

The kind of exercise and thoughtfulness that people like David Eddy at Stanford go through in calculating the utility of screening must, at the very least, be applied in this area, where the effects of

a screen or a nonscreen are much more profound because they really involve the future livelihood of people.

Mr. GORE. I would like to thank all of you for being here. I said a couple of times yesterday, I haven't said today, that one of the reasons we are pursuing this so avidly in a series of hearings is the anticipation on the part of the subcommittee that we are going to see a lot more of this genetic screening technology, particularly with the use of HLA antigen screening and the pre-existing incentives that many employers have and feel they have to use techniques as soon as they become available.

And the way in which these issues have been joined and addressed in this specific case, I think can help us, I hope can help us deal more sensibly and rationally with similar issues as they occur in the future, not to diminish the urgency of this particular issue, which I think is substantial.

I think your testimony here today has been extremely helpful in dismissing some of the irrational elements that cloud understanding of these issues. I thank you all for participating. Thank you very much.

Our next witness is Dr. Bruce W. Karrh, medical director, of the Du Pont Co., and without objection, Dr. Karrh, your prepared statement will be included in full in the record. At this point, we invite you to proceed with any or all of it as you see fit.

I would like to welcome you to the subcommittee. You are accompanied by?

Dr. KARRH. Mr. Gerald Hapka, counsel from the Du Pont Legal Department.

STATEMENT OF DR. BRUCE W. KARRH, M.D., E. I. DU PONT DE NEMOURS & CO., INC., ACCOMPANIED BY GERALD A. HAPKA, ATTORNEY

Mr. GORE. Welcome. Glad to have you as well. Please proceed with your statement.

Dr. KARRH. Thank you, Mr. Chairman. Let me start off by saying I don't mean to be unresponsive to the questions that you raised in your opening statement today, but my written testimony which has been submitted to the committee as well as the statement that I will give verbally today, were written in response to the specific issues that you raised in your October 1 letter to me.

I will, however, be glad to try to answer any questions on your opening statement at the end of my oral statement.

I have been in the practice of medicine for approximately 19 years, both in the military, in private practice and as an occupational physician for Du Pont. My experience has been spelled out in greater detail in the written testimony which you have copies of.

What I would like to do today is summarize that written testimony and direct my comments to questions that were raised in your letter to me. I also want to comment on the methods we, at Du Pont, employ to determine whether or not our employees are sensitive to the substances to which they might be exposed in the workplace. It is Du Pont company policy to provide a safe and healthful workplace for employees.

We do not exclude certain individuals from job assignments as a substitute for achieving safe exposure levels for our employees.

Du Pont does not conduct genetic screening of its employees, for purposes of employment, job placement or promotion, and I am not aware of any other company which does.

Du Pont does not conduct any cytogenetic surveillance of its employees.

Du Pont does offer to test black employees and black job applicants for the sickle-cell trait. Du Pont does not use the sickle-cell blood test to screen for employment, job placement, or promotion. This testing was initiated at the request of a group of black employees in the Wilmington, Del., area.

Positive test results are provided only to the individual for use with his or her personal physician. The results are retained in the employee's medical file on a confidential basis.

However, as set out more completely in my written testimony, even this use of sickle-cell testing for the private use of our employees has been publicly misconstrued.

As a preface to my remarks, let me state my understanding of genetic and cytogenetic screening. Genetic screening tests are those which determine whether a person has a heritable physiological abnormality.

Cytogenetic screening tests are those where human chromosomes are cultured and examined microscopically to determine whether they have been altered by outside influences, such as chemical exposures.

With that as background, I would like to elaborate on some of the concerns raised in your letter.

Your letter states that, "Diagnostic screens for particularly high-risk groups are being increasingly utilized in American industry," and that application of this testing technology is still in the developmental stages.

The concern implicit in these statements is that when an individual's health status plays a role in important employment decisions, such as hiring, placement, and promotion, the assessment of that person's susceptibility to particular workplace exposures should be based on criteria which are sound scientifically and judiciously applied.

The concern is legitimate, and one with which I wholeheartedly concur.

Accepted medical screening tests are an important part of occupational medicine and, though genetic tests may be useful in a research setting, their utility in occupational medicine has not been demonstrated.

Thus, aside from any ethical or policy questions they raise, they are simply not practical tools and to the best of my knowledge, are not being done in industry. Instead, occupational physicians use the same well-established medical tests employed by private practitioners serving the general public to assess the health of employees.

In addition, certain biological monitoring tests are used to assure that workers are not absorbing harmful amounts of substances to which they are potentially exposed.

Your letter raises six questions, the first three of which ask: Whether existing genetic tests are accurate; whether they are ap-

appropriately predictive; and what level of predictability from these tests is desired.

Although I am not an expert in the scientific methodology used to develop these tests nor on their general applicability, I am familiar with the utility of the serum alpha-1-antitrypsin SAT test and the glucose-6-phosphate dehydrogenase, G-6-PD, tests in an occupational medical setting, and with the sickle-cell test I previously mentioned.

Generally speaking, they are screening devices which may indicate a need for further testing. So far as their ability to predict susceptibility is concerned, Du Pont could not conclude that its use of the SAT or G-6-PD tests provided accurate or reliable predictability of hypersusceptibility.

Thus, we did not find the G-6-PD or SAT tests useful in an occupational setting and, therefore, we no longer do them. Rather than rely on such screens, we believe well-established medical tests, combined with periodic physical examinations, provide us more reliable information on whether or not an employee may be safely placed in a particular job.

In the fourth question, you ask if the workplace should be altered to eliminate the potential hazard to high-risk groups, what costs would be involved to do this, and if screening is used as a substitute for improvement in workplace quality.

As I mentioned previously, the Du Pont Co. does not exclude individuals as a substitute for achieving safe exposure levels. If individuals are adversely affected by the chemical exposure in their jobs, Du Pont will investigate the situation and then implement appropriate engineering controls, work practices, personal protective equipment or a combination of all these changes as necessary to eliminate the exposure.

The type of controls implemented are balanced according to the best control methods for the hazard, the number of individuals affected, the type of effects and the feasibility of the controls. There are situations where, as a last resort, it may be necessary to exclude individuals or a group from a particular work area.

There are also instances where some employees are more sensitive to certain chemical exposures than are others. If that sensitivity creates a health risk to the employee, and workplace controls are not feasible, we will provide employment in another area without loss of pay or employment rights, if at all possible. Thus, at Du Pont we do not substitute medical testing and removal for improvements in workplace quality.

Your remaining questions ask whether workers should be permitted to assume the risks involved in their job.

An employer, in our opinion, has the responsibility to provide a safe and healthful workplace. Du Pont does not permit workers to assume the risks of bodily harm from known or predictable hazards of occupational disease or accident.

This is the case regardless of any potential financial loss incurred by the company or the employee. If we cannot manufacture a product without creating undue risks to our employees, we will not manufacture it at all. We will not knowingly allow our employees to work at increased risk of adverse health effects due to their job.

To conclude my remarks, I would like to summarize my view of this subject. As I stated previously, Du Pont is not conducting any genetic testing other than the sickle-cell test, nor, to my knowledge, is any other company. I am aware that a very small amount of cytogenetic testing has been done, but none by Du Pont.

Where so-called genetic screening tests have been used by Du Pont, the use has been solely to determine if they have the capability to predict individuals who may be unduly sensitive to particular workplace exposures.

We are not convinced that such screening offers a benefit over existing programs in which we employ well-established medical tests. The number of chemicals which present a problem for hypersusceptible individuals is small. The few workers who have been identified as hypersusceptible can generally be offered alternative and equivalent job assignments.

Thus, any potential adverse impact from chemical hypersusceptibility is neither significant nor widespread.

I would like to add at this point in my oral statement, Mr. Chairman, that with respect to the reproductive hazards, I concur with your statement to the previous witnesses that in-utero exposure of the fetus is of much more concern to occupational physicians than is the preconception exposure of the adult male or adult female.

Mr. GORE. Let me interrupt you there and say that that was a question rather than a—intended to be a question rather than a statement, of an exploratory nature, seeking corrections of any misconceptions that it might contain.

I don't feel qualified to make that conclusion. I had that preconception at the time I posed that query. I am not sure I still have it after listening to the panel of witnesses. I believe the uncertainties involved are substantial and that there are other reasons to question that preconception.

But we can talk about that after you complete your statement.

Dr. KARRH. Let me conclude by saying that protecting the reproductive apparatus of the adult male or adult female is done in exactly the same way and we would protect any other physiological function of the adult male or adult female worker in the same manner.

We set our workplace exposure levels for what is potentially the most toxic hazard and what would be the most sensitive organ system of the employee. However, we do have difficulty when we have a fetus which is in the workplace as a third party and we either don't know that it is there, we don't have data to indicate what the risks are, or we have data but we have not been able to set an acceptable exposure level for the fetus.

But our means for protecting, whether it is reproductive apparatus at risk, respiratory apparatus, or cardiovascular apparatus, would be the same. The management of Du Pont has always been committed to leadership in employee health and safety protection programs and we intend to continue that commitment.

I wish to thank you for the opportunity to present testimony and will try to answer any questions.

[The prepared statement of Dr. Karrh follows:]

PREPARED STATEMENT OF B. W. KARRH

I am Dr. Bruce W. Karrh, Corporate Medical Director of the Du Pont Company. Prior to becoming medical director, I was a military physician for three years and then engaged in the private practice of medicine in Alabama for five years. I was employed by Du Pont in 1970 as plant physician at our Richmond, Virginia, location for almost three years. In that job, I performed all the tasks generally assigned to a Du Pont Company plant physician. These included conducting preemployment and routine physical examinations of employees, advising employees and management regarding health-related issues, and carrying out any special medical surveillance programs required by law or recommended by the Corporate Medical Division. In 1973, I was transferred to Du Pont's Haskell Laboratory for Toxicology and Industrial Medicine as Research Manager in Environmental Sciences, with responsibility for industrial hygiene and physiological evaluations. Following my work at Haskell, I was named Assistant Corporate Medical Director in 1974 and held this position for three years before occupying my present assignment in 1977. As corporate Medical Director, I am administrator of the Du Pont Company's occupational medical program and am responsible for developing and assisting in implementing corporate policy related to employee health matters. My office also has responsibility for consultation with and assistance to plant physicians and managers on health matters.

According to the letter inviting me to testify here today, the Subcommittee is interested in evaluating "the scientific legitimacy and legality of medical and genetic screening programs in the workplace" and whether current practices are sufficient to protect workers against "invidious discrimination on the basis of some physical trait". I have also been asked to direct my testimony to a number of questions relevant to these topics. Before testifying on these matters, I would like to review generally some of the pertinent Du Pont Company policies.

First, it is Du Pont Company policy to provide a safe and healthful workplace for its employees. The Company does not exclude certain individuals from job assignments as a substitute for achieving safe exposure levels for its employees.

With the exception of sickle cell trait tests, the Du Pont Company is not conducting genetic screening of its employees, and I am not aware of any other company which is.

Du Pont does not conduct any cytogenetic surveillance of its employees.

Since 1972, Du Pont has been testing Black employees and Black job applicants for the sickle-cell trait. Du Pont Company does not use sickle-cell blood tests to screen for employment, job placement or promotion. The Company promotes, then assessment of that person's susceptibility to particular workplace exposures should be based on criteria which are sound scientifically and judiciously applied.

The concern is legitimate and one with which I whole heartedly concur, but it has been prompted by a misperception of current industrial medical practices. To the best of my knowledge and contrary to the Subcommittee's assumption, industry is not conducting any genetic testing, let alone a substantial amount. Though genetic tests may be useful in a research setting, their utility in occupational medicine has not been demonstrated. Thus, aside from any ethical or policy questions they raise, they are simply not practical diagnostic tools. Instead, occupational physicians use the same standard, well established medical test employed by private practitioners serving the general public. The only exceptions to this are certain biological monitoring tests which are used to assure that workers with potential for exposure to certain harmful substances are not assimilating these into their systems.

To put industrial health programs in the proper perspective, I think it would be helpful to describe Du Pont's occupational health program to you and explain the role that employee medical data plays.

Our program is comprehensive. There are four principal components of it, which include:

(1) Toxicology: Forty-six years ago, Du Pont established the Haskell Laboratory for Toxicology and Industrial Medicine to study the toxicity of chemicals the Company uses, makes or sells. Haskell now studies about 300 substances a year to determine if they may be hazardous from an occupational or environmental standpoint. The Haskell Laboratory is equipped to study both acute and chronic hazards, and its battery of available tests allows us to assess a chemical's potential for causing mutagenic, teratogenic or carcinogenic effects. Haskell's findings are a critical factor in management's decisions on whether or not to produce a compound.

(2) Industrial hygiene: Besides obtaining toxicity data, Haskell Laboratory recommends appropriate industrial hygiene practices and controls for use at our plant sites. Du Pont's Safety and Fire Protection Division and its Engineering Services

Division assist in the development and implementation of these protective measures.

(3) Occupational medicine: Du Pont has approximately 70 full-time and 50 part-time physicians and 200 registered nurses. The occupational physicians' job is to assure that an employee or prospective employee can safely perform the job to which he or she is assigned. In this connection, they (1) conduct pre-employment physical examinations, (2) periodically re-evaluate the employee to detect signs of adverse health effects which could be due to the job or which may increase the risk from working the job, (3) treat any work-related illness or injury and (4) assist the employee with his or her personal health care and health planning.

(4) Epidemiology: Since 1956, the Medical Division has collected epidemiological data on the causes of diseases or deaths among our employees and deaths among pensioners. These studies have been an important part of Du Pont's program to control hazards. Our epidemiologists analyze selected illness and death rate data periodically to determine whether an excessive incidence of a disease has occurred at a Du Pont site. Additionally, they conduct studies of groups of employees who have had exposure to specific potential occupational hazards in order to identify any adverse effects on health, and to determine if existing safety procedures have been effective. Our studies have confirmed that the incidence of cancer among Du Pont employees is approximately 80 percent of that of the general population. We believe that analysis by epidemiologic technique is a good measure of the effectiveness of our occupational health programs. Such technique is also useful in detecting potential adverse effects, not only from chemical exposures, but life style, stress and other factors that might not otherwise be predicted.

To clarify our testing practices further, let me describe more fully the occupational medical component of our health program. As I stated previously, each job applicant receives a pre-employment physical examination. The examination itself is essentially the same type physical routinely given in private medical practice. It includes a comprehensive medical history, a series of blood tests, such as a complete blood count and various blood chemistry analyses, EKG, chest X-ray, pulmonary function test, eye and hearing examinations, and a physical exam. Management receives a recommendation from the examining physician about the employee's overall ability to handle a particular job safely. For example, if the individual has a history of cardiac disease or back problems, he would not be assigned to a job where he would be required to do a lot of lifting. Similarly, an employee with a history of epilepsy would not be assigned a job driving a vehicle.

After an employee has been assigned to a particular job, he or she will receive a follow-up medical examination. Employees over 40 years of age are re-examined annually; those 40 and under, biennially. The follow-up physicals are compared to the pre-employment "baseline" examination, and if there are any significant changes in the individual's health, he is informed. If he is experiencing a health problem because of his job assignment, we take whatever corrective measures are necessary. Our efforts are preventive—discover the situation before it becomes a problem—then eliminate or control it.

A key feature of our medical program is biological monitoring. DMF (dimethylformamide) and DMAC (dimethylacetamide) are two good examples of chemicals where we conduct biological surveillance. Both chemicals are readily absorbed through the skin. Because of this, we have implemented stringent engineering and work practice controls and have an ongoing and extensive air monitoring program. As a backup to these tight controls, we conduct blood tests to assess liver function and urine metabolite tests to monitor each individual to determine whether or not the substance has been assimilated. These measures are precautionary—again, their purpose is to detect a potential exposure situation well before it becomes a problem. If we discover that there has been bodily uptake of a substance being monitored, we re-examine our control measures and take corrective action.

As you can see from the description of our medical program, we use standard or specialized medical monitoring tests to assess the health of our employees—not genetic screening. Unfortunately, however, a great deal of attention was focused on Du Pont and genetic testing by a front-page New York Times article which appeared over a year ago. The article wrongly implied that Du Pont used sickle-cell blood tests to screen Blacks and that the results of these tests figured in employment decisions.

As I have already stated, this implication is absolutely false.

The Times misunderstanding was apparently precipitated by a misreading of one sentence from an article in the *Journal of Occupational Medicine* by Dr. Charles F. Reinhardt, Director of Du Pont's Haskell Laboratory for Toxicology and Industrial Medicine. Dr. Reinhardt's article discussed chemical hypersusceptibility, genetically-caused blood disorders, and how medical tests might permit detection of individuals

with blood disorders that could subject them to increased risk of harm if they were exposed to cyanogenic compounds. The sentence in question deals with a hemoglobin test, a standard blood test. No one with a low hemoglobin is assigned to areas of potential exposure to cyanogenic compounds, and Du Pont's benchmark for restricting someone from work with these chemicals is a hemoglobin of less than 14 g/100 ml of blood.

In keeping with his subject of genetic blood disorders, Dr. Reinhardt's article contained a sentence stating that individuals with the sickle-cell trait who had a hemoglobin below 14 g/100 ml of blood would not be permitted to work with nitro and amino compounds. Focusing on this statement, the Times' article implied a wholesale policy of excluding Black workers or limiting their assignments and promotions, which is not the case at all. If there remains any misapprehension from this article or any other source, let me set the record straight: Sickle-cell testing is not and never has been a factor in the hiring, placement, or promotion of Black employees. As stated earlier, these tests are performed solely as a personal service for our Black employees and play no role in hiring or job placement decisions. At Du Pont, if it is necessary to restrict an individual from working with nitro and amino compounds, that decision is based on factors such as the individual's hemoglobin, any history of cardiac disease, pulmonary function tests and the likelihood that an inadvertent excess exposure could occur.

In addition to the discussion of sickle-cell testing, Dr. Reinhardt's paper and the New York Times' article mention use of two other tests, the serum anti-trypsin deficiency (SAT) and the glucose-6-phosphate dehydrogenase (G-6-PD). The SAT is an enzyme test to measure the level of serum anti-trypsin in blood. In theory, if levels are low, it indicates a genetic deficiency and a potential for developing emphysema or chronic bronchitis. Similarly, the G-6-PD is an enzyme test to determine the levels of glucose-6-phosphate dehydrogenase in the blood. If the levels are low, then an individual may have an increased risk of hemolytic reaction and inadequate oxygen-carrying capacity when exposed to industrial amino and nitro compounds.

As I mentioned previously, apart from the sickle cell testing, Du Pont does not conduct any genetic testing. Previously, however, Du Pont used the SAT and the G-6-PD on a limited basis to determine whether they would be of value in protecting the health of susceptible employees. Use of the SAT was solely as a pilot project to see if it was a good predictive tool for discovering individuals who may subsequently develop pulmonary diseases. Use of the G-6-PD was also initiated primarily to assess its predictive capabilities. As is evident from this summary of our activity, Du Pont has had very limited experience with genetic testing.

I would like now to shift from Du Pont's experience to the questions asked of me by Congressman Gore. There are six of these; the first three ask: (1) Whether existing genetic tests are accurate; (2) whether they are appropriately predictive; and (3) what level of predictability from these tests is desired?

I am not an expert on the scientific methodology used to develop these tests nor on their general applicability. I am, however, familiar with their utility in an occupational medical setting. Generally speaking, these tests do just what their name implies—they are "screening" devices which may indicate a need for further testing. So far as their accuracy and ability to predict susceptibility is concerned, Du Pont could not draw any conclusions from its use of the SAT or G-6-PD tests and did not try to draw conclusions from the sickle-cell testing. Not enough testing was done with the SAT to provide a data base and the G-6-PD did not give us any additional information beyond what we had already learned from other standard medical tests. As a general matter, we have not found the G-6-PD or SAT tests useful in an occupational setting and prefer instead to rely on routine medical tests. We believe these well established medical tests, combined with periodic physical examinations, provide adequate data to ascertain whether an employee may be safely placed in a particular job.

Question four asks whether the workplace should be altered to eliminate the risk to high-risk groups. It further questions what costs would be involved to do this and whether screening is used as a substitute for improvement in workplace quality.

As I mentioned previously, it is Du Pont Company policy to provide a safe and healthful workplace for its employees. The Company does not exclude certain individuals as a substitute for achieving safe exposure levels for its employees. If a significant number of individuals were affected by the chemical exposure in their job, Du Pont would first investigate the situation and then implement the appropriate engineering controls. If these were not feasible, we would assess whether work practices or personal protective equipment could eliminate the problem or whether a combination of all of these changes is necessary. Obviously, it is in the Company's interest to solve the problem if a significant number of individuals are affected. The

type of controls implemented are balanced according to the best control methods for the hazard, the number of individuals affected, the type of effects, and the feasibility of the controls. Exclusion of an individual or a group of individuals is a last resort.

There are instances, however, where some employees are more sensitive to certain chemical exposures than are others. If that sensitivity creates a health risk to the employee, we will provide employment in another area without loss of pay or employment rights if at all possible. It is rare, though, to find large groups of people who have a sensitivity to a particular chemical. Sensitivity is usually confined to one or two individuals.

Questions five and six both ask whether workers should be permitted to assume the risks involved in their job.

An employer, in our opinion, cannot shirk its responsibility to provide a safe and healthful workplace by transferring this obligation to the worker. Du Pont's practice is not to permit workers to assume the risks of bodily harm from known or predictable hazards of occupational disease or accident. This the case regardless of any potential financial loss incurred by the Company or the employee. If we cannot manufacture a product without creating undue risks to our employees, we will not manufacture it at all. We will not knowingly allow our employees to work at increased risk of adverse health effects due to their jobs.

To conclude my remarks, I would like to summarize my view of this topic. So far as I am aware, genetic or cytogenetic tests are not being conducted by industry. As I stated previously, Du Pont is not conducting any genetic testing nor, to my knowledge, is any other company. I am aware of only a very small amount of cytogenetic testing being done, and none of this has been conducted by Du Pont. Where so-called "genetic screening tests" have been used by Du Pont, their use has been solely to determine if they have the capability to predict which individuals might be unduly sensitive to particular workplace exposures. It has been our experience that these genetic screening tests are not sufficiently precise for occupational medical use and that standard medical tests give us more reliable information about which employees may have a problem from exposure to certain chemicals than do genetic testing. However, if genetic screening tests are developed that in our opinion will provide accurate and reliable information about an employee's potential hypersusceptibility to a substance present in the workplace and if the tests are more reliable than existing medical tests, we will, of course, seriously consider the use of such tests. Our testing programs are designed to identify individuals who need protection from chemicals they might contact in the workplace and are not used for purposes of discrimination nor as an excuse to avoid making appropriate workplace modification to accommodate these individuals.

The number of individuals for whom exposures present a hypersusceptibility problem is extremely small. Additionally, the number of chemicals which present a problem for hypersusceptible individuals is extremely small. The workers so affected can generally be offered alternative and equivalent job assignments. Thus any potential adverse impact from chemical hypersusceptibility is not significant or widespread.

The management of the Du Pont Company has always been committed to leadership in employee health and safety protection programs. These have included pioneering toxicological testing of chemicals at Haskell Laboratory, workplace controls to prevent hazardous exposures, epidemiological studies, industrial hygiene monitoring, and regular physical examinations for all employees. We intend to continue our commitment to provide the most progressive occupational health program available in industry today.

Mr. GORE. Fine. We thank you for your statement and we appreciate your appearance here today.

On page 7 of your testimony, you mention your concern about back injuries. Yesterday, we heard a good deal of testimony about low back X-rays as predictors of back injuries.

Do you ever use back X-rays for such purposes?

Dr. KARRH. In the past, when many other industries were using back X-rays as preemployment predictor these were utilized to some extent within the Du Pont Co. They have not been utilized since the early seventies as a test.

If we have an employee who is complaining of a back problem, then the physician will decide whether or not an X-ray is indicated

for that particular situation. But back X-rays are not used routinely at all.

Mr. GORE. And not used in a preemployment context?

Dr. KARRH. That is correct.

Mr. GORE. Your testimony states on page 7 that you give all job applicants chest X-rays. Do you give any other X-rays to all job applicants?

Dr. KARRH. Not routinely, no. Just chest X-rays.

Mr. GORE. Do you include X-rays in the followup medical examinations?

Dr. KARRH. Yes.

Mr. GORE. What kind?

Dr. KARRH. Chest X-rays only.

Mr. GORE. How do you guard against reproductive hazards associated with X-rays?

Dr. KARRH. We use low-dose film and we only make chest exposures. If a female applicant or female employee has reason to think she could be pregnant, and they are asked before the X-ray exposure is made, then we will use abdominal lead aprons as gonadal shielding to avoid any exposure that could occur to the uterus or to the fetus.

Mr. GORE. Do you think that is effective?

Dr. KARRH. Yes. This is the same routine used in hospitals when routine chest X-rays are made and we follow the same procedures.

Mr. GORE. Do you provide preemployment or followup X-rays to fertile men?

Dr. KARRH. We provide the periodic physical examinations as noted in my testimony every year to employees over 40 years of age and every 2 years to employees 40 years of age and under and these are the same for male employees as for female employees.

They do include as a part of that examination a chest X-ray.

Mr. GORE. Do you worry about reproductive hazards in such instances?

Dr. KARRH. Always when you are using X-rays you have a concern about the potential effect on the reproductive apparatus. Using low-dose film, modern X-ray equipment and modern techniques makes the likelihood of that very low.

The exposure from a routine chest X-ray properly done is very low.

Mr. GORE. Do you ask men prior to X-rays whether or not they intend to parent children at any time in the near future?

Dr. KARRH. No, and we don't ask women if they intend to. We ask them before we make the X-ray exposure if they are pregnant at that time, or if they suspect they are.

Mr. GORE. We heard testimony from the last panel that X-ray exposure to the father of a child yet to be conceived may pose a greater risk to the offspring than the risk associated with X-ray exposure to the fetus in the uterus. Do you have any reason to challenge that testimony?

Dr. KARRH. I have no reason to challenge it at all, and I can't speak for the previous witnesses, but I think their concern was in the low back X-rays, not in routine chest X-rays removed from the area of the low back.

Mr. GORE. No, I am talking about the immediate prior panel.

Dr. KARRH. I heard their testimony, but I was thinking that was in response to the question on low back X-rays.

Mr. GORE. I had cited the example used in yesterday's testimony.

Dr. KARRH. But as I said, I cannot speak for their testimony.

Mr. GORE. What about the case of lead exposure, do you ask women if a pregnancy might be involved?

Dr. KARRH. I am not sure I understand your question, Mr. Chairman.

Mr. GORE. With respect to a company where lead exposure occurs, do you think that company should—would you recommend that such a company adopt a similar procedure to the one you use prior to X-rays?

Dr. KARRH. Lead presents a unique problem because lead is stored within the body and retained within the worker's body for relatively long periods of time. There is good evidence, most of it is human evidence from the turn of the century, very old data, that indicates that lead does have an effect on the developing embryo or fetus, if the mother has been exposed to relatively high concentrations of lead and has a body burden of lead.

Lead is one of the compounds that many companies, including my own, have a policy that women of child-bearing capability cannot work in areas in which there is potential for exposure to lead or its salts above a certain predetermined level.

Mr. GORE. On pages 7 and 8 you refer to corrective action which the company will take under certain circumstances. In one instance, you mention that such corrective action will be taken if an employee is experiencing a health problem because of his job assignment.

In another instance, you speak of urine metabolite tests and blood tests to assess liver function.

Does such corrective action include medical removal?

Dr. KARRH. It may, if it is determined that that person is experiencing some adverse health effect as a result of the job exposure.

Mr. GORE. What else might it include?

Dr. KARRH. I am not sure I understand what your question is.

Mr. GORE. What other corrective action?

Dr. KARRH. We would correct what caused the potential excess exposure. We would also evaluate other workers who had potential exposure in that same workplace to see if they, too, were experiencing any adverse health effect and we would correct whatever the source of that exposure was, so we would no longer be exposing people to an excessive amount.

Mr. GORE. Would medical removal be the first option and attention to the causative factor, second option?

Dr. KARRH. It would be done simultaneously. We would remove the person from risk so we wouldn't be doing anything to harm his or her health while we sought the remedy to the situation.

But we would not delay remedying the situation because we had removed the person. We do not feel we could leave the person at risk of continued adverse health effects while we seek a solution to the problem that caused it in the first place.

Mr. GORE. Suppose you removed the person from the workplace, or the part of the workplace, then conducted a review of the other employees in that workplace, and the evidence did not firmly estab-

lish the presence of similar harm in any of the others, would the option of addressing the cause of harm to the first individual then be forgotten about?

Dr. KARRH. No. We would investigate the first individual to see what could have caused that person to have experienced the adverse health effect, investigate the job they were doing, their workplace, the way they handled the job, the types of equipment that they were using and try to determine why they were different from the others as far as their experiencing some health effect from the job.

Only after we had totally excluded the possibility that the job itself was causing it and not just the individual's susceptibility to it would we take any exclusionary action.

But it is very seldom really that removal has to be done; removal from a job is not a frequent occurrence because of individual susceptibilities.

Mr. GORE. In what percentage of cases would corrective action consist of medical removal?

Dr. KARRH. I can't give you a percentage. I can just tell you it would be in very few cases that permanent medical removal would be the preferred course of action.

Mr. GORE. How predictive are liver function and urine metabolite tests?

Dr. KARRH. The liver function tests are not predictive at all. The liver function tests measure physiological changes in the ability of the liver to function, so they are not a predictive test.

The biological monitoring tests are not predictive at all. They are tests for the actual absorption of the material for which you are testing. In the two examples I cited, we check for metabolites of dimethylformamide and dimethylacetamide in the urine of employees who may have been exposed.

The only way that the metabolites can get there is for the person to have been exposed.

I should add, Mr. Chairman, that these tests are really a check on two parameters. One is how effective have our controls been to make sure that we are adequately protecting our employees. Second, to make sure our employees are not suffering any adverse health effects as a result of their jobs.

Mr. GORE. I guess the question is how indicative of those two factors are the tests?

Dr. KARRH. The metabolite tests are very indicative, because nothing else will cause the metabolite to be there. If the metabolite is present in the urine, in the case of the two I cited, if it is present in the urine above a level we have previously determined to be a level that would result from a safe exposure, then we know that person has been overexposed. The liver—

Mr. GORE. So you get no false positives?

Dr. KARRH. We have not had any false positives.

Mr. GORE. You might get false negatives?

Dr. KARRH. To my knowledge, we haven't any on those tests either, but that is a possibility. The liver function tests are not specific tests, all they tell you is that the liver has some dysfunction, it is not functioning properly for some reason.

It does not tell you why it is not functioning properly. But by using a battery of tests, doing the investigation we do, and using the metabolite test we do, we can decide whether or not the workplace exposure may have been the cause of the abnormal liver function test.

Mr. GORE. Moving on to a related area, what is Du Pont's policy regarding medical removal of women in the area of reproductive hazards?

Dr. KARRH. We have some few jobs where we have had to exercise what we call special controls because of the embryo-fetotoxic potential of a chemical substance. Out of the 2,500 chemical substances that Du Pont reported to the EPA. For the Toxic Substances Control Act inventory, we have identified only seven chemicals that we do have to exercise special controls because of their embryo-fetotoxic potential.

In cases where we do have to exercise special controls, we will start first with engineering controls to try to reduce the exposure at its source. If we are not successful in reaching a safe exposure level or if we don't know what a safe exposure level is, we will go to personal protective equipment, or work practice controls, in combination with engineering controls.

If those three methods are not successful, we may have to exercise medical removal of women of child-bearing capability.

Mr. GORE. What are the seven chemicals?

Dr. KARRH. The first two are listed in my testimony on the top of page 8, dimethylformamide and dimethylacetamide. Both of those have a threshold limit value set by the American Conference of Governmental Industrial Hygienists and picked up by OSHA, of 10 parts per million in air, but they are readily absorbed through the skin.

If we have a workplace in which employees are exposed to levels that do not exceed 10 parts per million in air and there is no significant opportunity for liquid contact with the skin, then both men and women of child-bearing capability are allowed to work in such areas. If we exceed 10 parts per million in air, although we have almost no places that do, or if there is opportunity for significant liquid contact with the skin, which there are some jobs where that can occur, then women of child-bearing capability would be excluded.

The third one is formamide, which has a threshold limit value of 20 parts per million. Our internal limit for women of child-bearing capability is set the same as for dimethylformamide and dimethylacetamide, 10 parts per million in air with no opportunity for significant liquid contact with the skin.

The third one is ethylenethiourea. It is also carcinogenic and is controlled at a very low level because of its potential to cause cancer of the thyroid. Women of child-bearing capability are not allowed to work jobs in which they can be exposed to ethylenethiourea.

Fortunately, those are very few jobs. The fourth one is hexafluoroacetone; which has a threshold limit value of 0.1 parts per million, set by the American Conference of Governmental Industrial Hygienists based upon its effect on animal spermatogenesis in some work done by Du Pont.

This is the reason for the threshold limit value that has been set at that low level, but it also has an effect on the fetus at levels below that, based upon data that we have.

In jobs in which there is potential for exposure to hexafluoroacetone, women of child-bearing capability would not be able to work.

The sixth one is lead and its salts, and this includes a whole family of compounds. Women of child-bearing capability are allowed to work in jobs in which the atmospheric concentration of lead does not exceed 5 micrograms per cubic meter of air or in which the blood level of exposed workers will not exceed 30 micrograms per 100 grams of blood.

The seventh one is ammonium perfluorooctanoate, abbreviated FC-43, and that is a new one based some preliminary data that was developed the first of this year. We found that it did cause an abnormality in the eyes of rats in a preliminary study that was done, at the levels that we thought could be found in the workplace. I am sorry, counsel just reminded me that we did not find it but another company who is our supplier found it and advised us.

We felt we had to take the appropriate action until we could further delineate exactly what was the risk to the fetus in those cases. That chemical is still on our list. We currently have studies under way to delineate what is exactly the risk to the human fetus.

Mr. GORE. Let's focus in on the case of hexafluoroacetone, Du Pont conducted a study showing that it caused harm to male spermatogenesis.

Dr. KARRH. In laboratory animals, yes.

Mr. GORE. In laboratory animals?

Dr. KARRH. Yes.

Mr. GORE. And based upon the damage found to spermatogenesis, the company decided to exclude fertile females from coming into contact with this chemical?

Dr. KARRH. No, sir.

Mr. GORE. Correct my understanding.

Dr. KARRH. The TLV, threshold limit value, by the American Conference of Governmental Industrial Hygienists, was set based on its effect on animal spermatogenesis. The effect it has on the developing fetus is a separate effect from its effect on the sperm.

Mr. GORE. But that was—

Dr. KARRH. That was also determined by laboratory animal studies, separately from the spermatogenic effect.

Mr. GORE. I see, all right.

Dr. KARRH. I probably confused you by the way I said that. In addition to having a spermatogenic effect, it also has an embryo-fetotoxic effect. The special controls which may mean exclusion in some cases, were implemented because of its effect on the embryo or fetus, not because of its effect on the sperm.

But the TLV was set because of its effect on the sperm. The TLV holds for adult female workers not of child-bearing capability and would also apply to adult females who were of child-bearing capability were it not for the fetotoxic effect.

Mr. GORE. The fetotoxic effect was not partly inferred from the spermatogenic effect.

Dr. KARRH. That is correct, it was not.

Mr. GORE. All right. Now, are fertile males excluded from contact with hexafluoroacetone?

Dr. KARRH. No, because we can keep it below the 0.1 part per million level which has been determined a safe level for spermatogenic effects.

Mr. GORE. But the level for fetotoxic effects is lower than that?

Dr. KARRH. That is correct, based upon animal data that we have.

Mr. GORE. And who established that level?

Dr. KARRH. The 0.1 was established by the American Conference of Governmental Industrial Hygienists. The no-contact for the fetus is an internal Du Pont level based upon the data we have.

Mr. GORE. Based upon which data?

Dr. KARRH. The animal test data that we have that indicates it does have an embryo-fetotoxic effect.

Mr. GORE. Is that data quantifiable?

Dr. KARRH. Our toxicologists think it is, but not to a specific number because they cannot extrapolate the data that they have from these animal studies to a level that they can be applied to the human fetus.

Mr. GORE. Was the fetotoxic data developed by Du Pont?

Dr. KARRH. Yes. To my knowledge, it was. I have not looked at it lately but I think it was.

Mr. GORE. I see. What is your opinion concerning the testimony regarding reproductive hazards to men? You heard the first panel.

Dr. KARRH. I think there are some hazards that can be transmitted to the embryo or fetus by exposures of the male. This is a very new area which is poorly understood at present. Some of the studies that have been reported indicate that this area needs more research.

Mr. GORE. Are you contrasting the poor nature of the understanding in this area with the excellent nature of the understanding in the fetotoxicity area?

Dr. KARRH. I don't think we can say it is an excellent understanding in the fetotoxic area. I think it is a little better understood area than the male-mediated reproductive hazards. You are dealing with two different entities. In one, you are dealing with the adult worker, whether it is male or female, and protecting against the most sensitive physiological function or organ system that that adult worker has, whereas in the other case, you are concerned with protecting against an unborn fetus that shows up in the workplace. The employer may or may not know that the employee is pregnant, the employee may or may not know she is pregnant.

The period of damage to the fetus or to the embryo is during the period of organogenesis, day 18 through day 60. Many women do not know they are pregnant within the first 18 days after fertilization of the ovum. Consequently, damage to the embryo or fetus could occur before pregnancy was recognized.

Mr. GORE. Are you confident enough in animal extrapolation that you wouldn't mind being exposed to the TLV level of hexafluoroacetone on a daily basis?

Dr. KARRH. I am confident enough in it that I would not mind being exposed to it on a daily basis, that is correct. The extrapolation

tion of animal toxicity data to man is a standard toxicological method used to set acceptable workplace exposure levels.

The majority of the TLV's developed by the American Conference of Governmental Industrial Hygienists and incorporated into the OSHA law are based on animal data extrapolated to man.

Mr. GORE. Back to the reproductive hazards to men, what concerns do you have about the possibility of birth defects caused by exposure of men to reproductive hazards?

Dr. KARRH. We have the same concerns that we have about the exposure of females that may cause them to have children with birth defects, or by the exposure of females who may be pregnant that would cause the infant to be born with a birth defect. It is no different than our concern over any other toxic potential of our workplace.

That is why we try to control our workplace exposures to the level that will prevent employees from suffering any adverse effect on any of their physiological functions.

Mr. GORE. And what do you do about that at Du Pont?

Dr. KARRH. I am not sure I understand.

Mr. GORE. To deal with those concerns?

Dr. KARRH. We set our exposure levels at a level where we will not cause these physiological effects in our employees and we meet those either by engineering controls, work practices, personal protective equipment, or a combination of these, for the adult male or the adult female.

Mr. GORE. That statement evidences a high degree of confidence in the knowledge that you have about the effects of these chemicals, whereas Dr. Hunt described massive uncertainty in this exact area. We just don't know.

Dr. KARRH. I don't think we are any more knowledgeable than Dr. Hunt, nor is our confidence level any greater perhaps than is Dr. Hunt's. We do extensive toxicological testing. We test new chemical substances in animals before we start putting them into the workplace and, based upon that, we do an assessment of the risk and the toxic potential. We also put in a safety factor from what we find out from the animal data and then decide what is acceptable exposure level for that particular chemical in the workplace.

Then we design our workplaces to meet that level by engineering controls, if at all possible, supplemented by work practices and administrative controls. There is a great deal of uncertainty but I don't think that we are unique in that.

We have a full toxicology laboratory which does nothing but animal testing to try to help us decide what are acceptable workplace exposure levels. The OSHA Act incorporated as law, some of these levels that were set by exactly the same methods that we are utilizing.

Mr. GORE. The uncertainty, itself, has legal implications. The company—and I invite your comment, Mr. Hapka, if you don't feel uncomfortable in addition to giving advice to Dr. Karrh—is it fair to assume that the legal exposure of a chemical company to a cause of action brought by a child with a birth defect is significantly greater where the alleged exposure occurred in utero than

where the alleged exposure occurred prior to conception, because of the uncertainty involved?

In other words, because of the way the legal system deals with the uncertainty surrounding the evidence, you have to worry a great deal more about causes of action brought when the alleged exposure was in utero than you have to worry about causes of action where the alleged exposure was prior to conception.

Dr. KARRH. Let me address that first. Our concern is with the embryo-fetotoxic effects of our chemicals. It is not based upon the legal ramification or any subsequent loss.

Our concern is whether we are doing the right thing for our employees and their offspring and for society. An abnormal child, whether caused by a workplace exposure or by rubella, as we heard this morning, is a very devastating situation to a parent and, in the long term, to society.

We feel we have an obligation and, although we do have a legal obligation and have some concern. This is not our primary concern.

Mr. GORE. Well, I don't mean the question to have an accusatory tone. I like to think that my judgment as a Congressman of issues where I have to vote is not made on a political basis, but political perceptions often become a mode of analysis and insofar as legal exposure reflects preexisting and codified ethical judgments, it also becomes a mode of analysis for corporate legal departments.

At times, that mode of analysis may obscure commonsense and I am not accusing a company that uses that mode of analysis of having departed from commonsense. My question is merely intended to recognize the possibility that that can occur.

We saw it in the case yesterday where the unusual statute, the FELA statute in the railroad industry, caused a mode of analysis which led to results that are arguably irrational. I am not saying that is the case here, but as a matter of fact, does not the company have to worry more about legal exposure where the cause of action arises from an alleged exposure in utero and cause of action where the exposure, alleged exposure occurred prior to conception?

Mr. HAPKA. I don't really think we would analyze it in that way. First, I want to support what Dr. Karrh has said and that is that the basis upon which we go forward with the use or the marketing of a product has, as one of the cornerstones, the counsel that we get from the medical department and from our Haskell Laboratory in terms of its safety.

We do not balance that finally with whether or not we will be liable to a cause of action if there is any significant or even reasonable probability of harm.

We will not market a substance, and we have done that, if we cannot be sure it can be made or used safely.

The problems of proof are there. We have an employment relationship between us and the men and women that are in our employ. There is no such relationship with the fetus.

Mr. GORE. What does that mean?

Mr. HAPKA. We would be exposed to different kinds of liability under workers' compensation laws as opposed to not under workers' compensation laws.

Mr. GORE. Then I take it in a way, the answer that you are giving is yes, because the statutes prescribe a different standard.

Mr. HAPKA. But there is no real difference in our analysis of how we should treat the product.

Mr. GORE. But the fact is your legal exposure, in terms of dollars, is much greater in one case than in the other?

Mr. HAPKA. I would guess it is more immediate in the case of employees than in the potential for effect upon fetuses.

It is not a straightforward question.

Mr. GORE. Let me ask it another way. Has Du Pont ever faced cause of action for birth defects allegedly caused in utero?

Mr. HAPKA. Not to my knowledge.

Mr. GORE. The chemical industry has faced a number of such causes of action, has it not?

Dr. KARRH. I am not aware of any.

Mr. HAPKA. I don't know of any. It may have. We just do not know.

Dr. KARRH. I would reiterate, that although there is that legal possibility, we still feel that we have a responsibility to the employees and to society.

Mr. GORE. Pardon me.

Dr. KARRH. Although there is the legal ramification, our greatest concern is still our responsibility to our employees and to society in general.

Mr. GORE. Let me ask you two short questions.

Are there limitations on the amount that could be recovered under workmens' compensation cases?

Mr. HAPKA. Yes.

Mr. GORE. Are there any limitations on what can be recovered in an action brought by a child with birth defects?

Mr. HAPKA. No. Other than within the limits of proof.

Mr. GORE. No limit on the amount?

Mr. HAPKA. No limit on the amount.

Mr. GORE. I think that speaks for itself and may have some significance or may not. We will let the record speak for itself on that.

How much more evidence regarding reproductive hazards to men would be required before a change in policy would be recommended?

Dr. KARRH. Any evidence that we had that the male was being affected in a way that would be transmitted to his offspring would cause us to take action to reduce that potential exposure.

The same would be true for any female who had an exposure that was affecting her and was being transmitted on to her offspring without acting directly on the offspring itself.

Mr. GORE. Is your testimony that you have no evidence that the men exposed to these chemicals are facing reproductive hazards?

Dr. KARRH. We have no evidence that these seven chemicals that I listed have an effect on the sperm that is being transmitted to the male's offspring.

Mr. GORE. Let me ask one other question in this area. You do exclude all fertile women where you determine that a risk to the fetus that might be present exists?

Dr. KARRH. We exclude women of child-bearing capability from jobs in which there is a risk to the fetus if we cannot reach an

acceptable exposure level for the fetus or if we don't know what is an acceptable exposure level for the fetus.

Mr. GORE. What about a woman who is fertile, but has no intention of conceiving a child?

Dr. KARRH. This is one of the more difficult parts of the entire issue to deal with because there are many women, as we heard the previous panel state, who have no intentions of becoming pregnant.

Yet many pregnancies occur without the mother having the intention of becoming pregnant and because of that, when we take this action we have to take all women who are of child-bearing capability out of the areas and give them alternative, equivalent job assignments.

The exceptions are those women who are postmenopausal, Those who have had hysterectomies, and those who have had tubal ligations.

Mr. GORE. Has the company ever had any experience of that kind?

Dr. KARRH. Of what kind?

Mr. GORE. Where an unexpected pregnancy occurred to female employees in an area of risk?

Dr. KARRH. To my knowledge, we have not because we have females of child-bearing capability out of those areas where the fetus would be at risk.

I am sure we have had examples of female employees have gotten pregnant when they didn't want to.

Mr. GORE. How are you sure of that?

Dr. KARRH. I have had employees tell me they did not plan their pregnancy and they just became pregnant.

We have had some employees who were pregnant and unmarried. One has to assume in those cases—particularly if they tell you they did not want the pregnancy—they did not plan it.

Mr. GORE. On page 10, you mention decisions to restrict individuals working with HB is based on factors which include an individual's hemoglobin. Would you explain this?

Dr. KARRH. What page?

Mr. GORE. Page 10. You say that if it is necessary to restrict an individual from working with nitro and amino compounds, that decision is based on factors such as the individual's hemoglobin.

Dr. KARRH. Yes.

Mr. GORE. Could you explain that?

Dr. KARRH. Yes. It goes on to say in addition to what you just quoted, "any history of cardiac disease, pulmonary function tests and the likelihood that an inadvertent exposure could occur."

Mr. GORE. One of several factors.

Dr. KARRH. Yes. The reason for the hemoglobin test is that hemoglobin is the oxygen-carrying part of the blood and if a person has a lowered hemoglobin, their ability to carry oxygen is reduced.

Nitro and amino compounds—are substances which turn hemoglobin into a type that does not carry oxygen as efficiently as normal hemoglobin. If they already have a reduced oxygen-carrying capacity and are exposed to compounds that even further reduce their oxygen-carrying capacity, they could find themselves in dire medical circumstances quickly.

A person with a normal hemoglobin and without these other factors would be less likely to suffer these significant health consequences.

Mr. GORE. Is it Du Pont's policy to prevent an employee from working with nitro or amino compounds if his or her blood hemoglobin level is less than 14 grams per 100 milliliters?

Dr. KARRH. Our policy is that persons whose blood hemoglobin is less than 14 grams of hemoglobin per 100 milliliters of blood would not be assigned to jobs in areas in which they would be exposed to nitro or amino compounds.

Mr. GORE. How long has that policy been in effect?

Dr. KARRH. Many years. I cannot give you an exact time interval, but since the 1930's, 1940's, something in that time frame.

Mr. GORE. Are all employees subject to this requirement?

Dr. KARRH. Yes. But that is on a limited number of plants. Only one or two plants would be involved and therefore a limited number of employees.

Mr. GORE. All employees at the involved plants.

Dr. KARRH. All employees who could be potentially assigned to a job in a nitro or amino area, yes.

Mr. GORE. Has there ever been a time when any class of employees was not subject to this hemoglobin requirement?

Dr. KARRH. I am not sure I follow your question on that.

Mr. GORE. I think your earlier response will suffice to that question. Has the requirement always been made of white as well as black employees?

Dr. KARRH. That's correct. It is based on hemoglobin, irrespective of other personal factors.

Mr. GORE. Has the evidence necessary to make the determination with respect to hemoglobin always been gathered from white as well as black employees?

Dr. KARRH. The hemoglobin test has been done on white as well as black employees. If that is what you mean.

Mr. GORE. Always?

Dr. KARRH. Equally, yes.

Mr. GORE. What is the basis of the 14-grams-per-100-milliliter requirement?

Dr. KARRH. This is the lower level of normal hemoglobin in most laboratories. The levels of normal will vary between laboratories. Different laboratories may use different techniques and, based on the population they are serving since the norms are set on a population distribution, they may have varying levels. But 14 grams is generally recognized as the lower level of normal hemoglobin.

Mr. GORE. Do you feel that this is based on adequate research?

Dr. KARRH. It has been in existence for many, many years and there have been millions of hemoglobin tests done to set that distribution, so I think it probably is one of the better researched tests in existence.

Mr. GORE. There is a difference there. It may well be one of the most used tests, but the question is, are you confident that it is based on adequate research?

Dr. KARRH. Yes.

Mr. GORE. You were corporate medical director when Dr. Reinhardt published this controversial article in 1978 in the *Journal of Occupational Medicine*, entitled "Chemical Hypersusceptibility."

I want to ask you a couple of questions about that. First, let me read the paragraph which has given rise to the controversy:

Several screening tests for sickle-cell trait have now been developed and a number of mass screening programs have been conducted.

In Du Pont, as a service, we routinely offer all black employees a test for sickle-cell trait. If the test is positive, we will ask the applicant to check with his or her personal physician or a community health service.

At our Chambers Works plant, heterozygotes with a hemoglobin of less than 14 grams per 100 milliliters (of blood) are restricted from work involving the handling of nitro and amino compounds; if their hemoglobin is greater than 14 grams per 100 milliliters, no restrictions are made.

We generally employ individuals with sickle-cell trait who appear otherwise to fill job requirements.

That would give rise to the impression that the evidence on hemoglobin levels was in part an outgrowth of the sickle-cell screening and therefore not applied routinely to all employees.

Could you respond to that impression?

Dr. KARRH. Yes, that it is a misimpression. Let me go back to your original question. I was medical director when this article that subsequently became controversial was published.

It was not controversial in the medical community at the time it was published. That statement, looking back on it now with the benefit of about 3 years of being able to look at it and see how well it is worded, could possibly have been worded better. Maybe it would not have been as controversial as it has turned out to be.

But the controlling factor is the 14 grams of hemoglobin, not the sickle-cell trait. Dr. Reinhardt's paper was on hypersusceptibility and this section of several paragraphs was specific to sickle-cell anemia, which is the title of that section.

He was making the statement that the persons with the 14 grams of hemoglobin were restricted. Looking back on it, he probably should have said irrespective of what their sickle-cell test shows, because that is the practice we follow but the statement you read can perhaps be misinterpreted.

There are a number of other statements in that paragraph that indicate that sickle-cell test is not done as a means to decide whether or not a person can work in those areas.

Mr. GORE. What you are saying is that this was an unfortunate juxtaposition. It occurred immediately after discussion of sickle-cell trait and immediately prior to a second discussion of sickle-cell trait.

Dr. KARRH. I think it was an unfortunately worded sentence that several of us looked at before it was published and did not pick up the fact that it could be misinterpreted by others.

Interestingly enough during peer review the paper did not receive any comment from other physicians, none of whom picked that statement out and misquoted its intent or erroneously understood it.

Mr. GORE. We don't intend to attempt to resolve this matter, but in fairness, I would like to explore just briefly. In October 1980, the *Nation* published your letter to the editor challenging the accuracy

of articles written about your program for the New York Times and for that magazine.

In response to your letter, the author of those articles posed four questions—they were provided by the Nation concurrently with your letter to the editor.

I would like to ask you now, for the record, to respond to these questions so that we can clear up this matter.

First, if the Du Pont tests are only for the personal benefit of black workers, why are they mentioned in the Charles Reinhardt article, since it purportedly deals not with "personal health planning" for black workers, but with people who are said to be abnormally susceptible to chemicals?

Dr. KARRH. The title of the paper is "Chemical Hypersusceptibility" and there was some body of thought that people who had sickle-cell trait were more susceptible to certain chemical exposure than were others.

Dr. Reinhardt was trying to cover, for the medical community, the entire spectrum of genetic types of predisposing factors that could make someone hypersusceptible to chemicals.

Mr. GORE. Were any of the data on which you based your feelings about sickle-cell traits generated at Du Pont?

Dr. KARRH. No. We started testing black employees and black applicants in 1972 at the request of a group of black employees in the Wilmington area.

This was done purely for their own personal health care planning and edification. There have been letters exchanged between the New York Times and these black employees and between the author of the article in the Nation, Mr. Severo, and these black employees and even some telephone calls. These black employees have told the New York Times and Mr. Severo that they requested the tests which were done and, to their knowledge, the tests have not been used in a discriminatory fashion.

Mr. GORE. Let me finish this series of questions. Two is why are blacks the only racial or ethnic group singled out in the Reinhardt article?

Dr. KARRH. I think if you notice on that same page under glucose-phosphate dehydrogenase, he mentioned hereditary background a being a predisposing factor.

As far as why we only do sickle-cell testing on blacks, blacks were the only ones asking that it be done and they asked that it be done for their own health care planning use.

We have not had any other ethnic group ask us to do testing specific for any disease, illness, or trait they may have.

But if we were asked, we would consider whether or not it had application and whether it was something that would be helpful to the individual.

Mr. GORE. Three is how can Karrh stand by his original contention that the tests are "purely for the education and edification of the individual involved," when Du Pont's own public relations department admits the company does not have, and has never had, a uniform national policy for explaining the sickle-trait test to its black employees?

Dr. KARRH. I don't think that is an answerable question because I can't understand exactly what the latter part of the question is.

But our policy has been that a test would be given to black applicants and black employees and any positive results would be given to them for their own personal use.

It has not been used in any way in job-related decisions.

Mr. GORE. I think the relevant part of the question could be rephrased to simply ask do you have a company policy for explaining the sickle-cell test to your black employees?

Dr. KARRH. We had that when we first started in 1972, because we were not doing any other blood test except the hemoglobin or a specialized blood test required in areas in which the test would be specific for the exposure that the employee may have.

In 1974, all employees had been covered, so we stopped doing tests on employees once we had completed testing them. We continued doing the sickle-cell test on applicants.

In 1974, we added additional blood tests and at many sites, the physicians did not routinely tell the black applicant that sickle-cell testing was being done, but if the sickle-cell test was positive, they were given the results to give to their personal physicians for their own use.

Mr. GORE. Four is if no blacks have ever been transferred to other jobs because of their sickle trait, how does Karrh explain the statement of William Golt, president of the Chemical Workers Association, a company union, who said he knew of at least one black transferred because of the test?

Dr. KARRH. There is no way I can explain Mr. Golt's statement. I've heard the statement before. We have surveyed all of our plant physicians to find out if they ever made a job placement recommendation based on a sickle-cell test result and we did not have a single positive response.

It is possible that Mr. Golt knew someone who had a positive sickle-cell test, having been told by the employee, and the person was transferred for some other reason, perhaps a low hemoglobin or something else, and this was misinterpreted.

Mr. GORE. You mentioned in response to one of the earlier questions, in the discussion of people of Mediterranean background, the original article entitled, "Chemical Hypersusceptibility."

Are people of Mediterranean background screened for beta calcinia, as are blacks?

Dr. KARRH. No. Blacks are not either. The only screening test we do is sickle-cell trait and then only at the request of the applicant.

Mr. GORE. So what you are saying is that the asymmetry evidence by the selective test occurs because of the company's response to request for such a test and the company's desire to show sensitivity to that concern.

Dr. KARRH. I am not sure what you mean by the asymmetry of the test.

Mr. GORE. The fact that screening for sickle-cell trait is done and screening for other conditions such as beta calcinia is not.

That is what I mean by asymmetry.

Dr. KARRH. That's correct. We started doing the sickle-cell testing only because we were asked to by a group of employees who were at risk of having sickle-cell trait or sickle-cell disease and we were being responsive to their request.

We have not been asked by another identifiable group of employees to do similar testing for some other trait and we have not instituted such.

Mr. GORE. There have been written accounts of sickle-cell trait in whites, Mexican Americans, native Americans, Italians, Greeks, Turks, Arabs, and other nonblack groups.

Do you restrict the program to blacks because the original request came from blacks? Why isn't it offered to others if that is not the case?

Dr. KARRH. We restrict it to blacks because the original request came from them. At that time, Mr. Congressman, the United States itself was heavily involved in a lot of sickle-cell screening, and many State health departments were doing sickle-cell screening.

The military was doing sickle-cell screening. Black employees had seminars in Wilmington where they had experts come in and advise them to start sickle-cell screening.

Black employees, as a result of these seminars, requested that our periodic physical exam, which we provided anyway, be modified to include the sickle-cell screening test for their own personal use.

In order to accommodate that request from an identifiable group of employees, we included this test and it has been used only for their own personal use.

Mr. GORE. I have a number of other questions that I want to get for the record. First, how do you select people for sickle-cell screening? Just if they are black?

Dr. KARRH. When we first started, if they were black employees or black applicants, they would be told we were going to do the sickle-cell test. The sickle-cell test would be done and the results would be given to them.

Mr. GORE. Have you ever had any difficulty determining whether a person is black or not?

Dr. KARRH. If we have, we have not done the test. It has only been in those situations where we knew that the person was black that we did the test.

Mr. GORE. Now how?

Dr. KARRH. By appearance. Our present policy is that we tell all applicants, and we also have a pamphlet we give to them that says sickle-cell test is available if they want it. If they do, they are instructed to tell the lab technician when the blood is being drawn so a specimen can be drawn.

Mr. GORE. Is there a policy of informed consent surrounding these tests?

Dr. KARRH. All of the blood tests have a policy of informed consent. On our health history questionnaire, they sign a consent for us to draw the blood test.

Mr. GORE. At that time, were they told about the nature of the test or the nature of the screening?

Dr. KARRH. They are told that a series of blood tests, a chest X-ray and an urinalysis will be done to determine various physiological factors. It is part of the health history questionnaire and they sign that.

Mr. GORE. But they are not told what sickle-cell trait is or what its implications of its presence might be?

Dr. KARRH. They are just told that test will be done if they request it. The other tests are done without their requesting it.

Mr. GORE. Do you ask the applicant if they are already aware of their sickle-cell status?

Dr. KARRH. No. We just ask them if they would like to have the test.

Mr. GORE. How many have refused the test?

Dr. KARRH. I have no idea. This is not a test we have kept statistics or data on because we have been doing the test only for the employees own personal use. I could not tell you how many tests we have done.

Mr. GORE. There was an earlier statement that no one had turned it down. You are not sure that is the case?

Dr. KARRH. I don't think I made that statement.

Mr. GORE. I am not attributing it to you. Maybe that was the implication in my statement. In my reading in preparation for the hearing, I remember someone from the company being quoted as saying that.

Dr. KARRH. We said no one has been turned down for employment on the basis of that test.

Mr. GORE. An official of the company stated no one had refused the test. But you don't know that to be the truth?

Dr. KARRH. I am not aware of that.

Mr. GORE. What companywide education program exists for people found to have the trait?

Dr. KARRH. We have no companywide program. The employee is given the results of the test and referred to their own personal physician.

Mr. GORE. If these tests are conducted solely for the purpose of the employee's own use, presumably family planning, and the results are of no relevance to employee performance, why are the results entered in the employee's medical files at the company?

Dr. KARRH. Because we keep all medically related things in the employee's medical file which is retained by the site physician.

This includes any other blood tests that may be done, chest X-ray results, the physical examination results and the health history questionnaire that employees furnish us as a baseline so that in the future if an employee suffers some physiological disfunction or a decline in health status, we can look back and see at what point in time that may have occurred.

Mr. GORE. Who has access to medical records kept on a confidential basis?

Dr. KARRH. Until the OSHA Act gave somewhat unrestricted access, we had an internal policy that only medical personnel, either physicians, nurses or medical clerical personnel, could have access to medical records.

However, now with the OSHA Act, that has been much broadened to where with the consent of the employee, others can have access, and OSHA and any organization can have access without consent.

Mr. GORE. With consent of the employee. And who has access without consent of the employee?

Dr. KARRH. OSHA and any NIOSH. I am sorry. It is not the OSHA Act, but regulations under the OSHA Act.

Mr. GORE. Does anyone in the Haskell Laboratory for Toxicology have access to these records?

Dr. KARRH. No.

Mr. GORE. Do you have access to these records?

Dr. KARRH. I have access to the records on a need-to-know basis. The plant physicians are the custodians of the records on their plant and in order for me to have access to the records, I have to demonstrate to them a need to know.

Mr. GORE. You mentioned that DuPont established pilot programs in an effort to determine whether testing for serum alpha-1-antitrypsin [SAT] and glucose-6-phosphate de-hydrogenase [G-6-PD] deficiencies had any predictive value.

Would you tell the subcommittee a little bit about the procedures which you followed in conducting the tests.

Dr. KARRH. There was not a company wide program on either test. At one particular plant site, the plant physician decided to determine if either of these tests had any predictive capacity for determining whether or not persons may be at increased risk due to occupational exposures. In the case of the SAT tests, these tests were done and the results were filed in the medical record and nothing else was done with the tests or the results.

The intent was at some future date if the individual developed chronic lung disease, the plant physician, in going back to the medical record would find the results of these tests and be able to correlate them.

The G-6-PD test was started for a similar type purpose; to determine if they had any predictive capability. The employees were told at the time if their tests were positive.

Mr. GORE. Did the company notify its employees prior to commencement of these pilot programs?

Dr. KARRH. The SAT tests were done only on one plant and the G-6-PD on two and I cannot answer that question.

Mr. GORE. Did the company advise employees whose blood it was analyzing the purpose of the test?

Dr. KARRH. I cannot specifically answer that question. My opinion is that they were advised of the results of the test and of the purpose for it, but I was not at that plant, so I cannot answer it specifically.

Mr. GORE. Could you supply for the record response to the subcommittee to both of those questions after checking?

Dr. KARRH. Yes. Would you restate the question?

Mr. GORE. The first was whether or not the company notified its employees prior to commencement of the pilot programs. The plant medical staff did not advise employees of plans to conduct G-6-PD or SAT tests because the blood specimens that were used on the tests were obtained in the normal course of physical examinations and no explanation was given regarding the types of tests to be done on the specimens.

Second, did the company advise employees whose blood it was analyzing of the purpose of the test? As indicated above, employees were not advised of the purpose of the test before the test was conducted, however, where positive results were obtained, the em-

ployees were notified of such positive results and the possible significance of the results.

What counseling or educational program was established for employees who were found to have G-6-PD or SAT deficiency?

Dr. KARRH. None to my knowledge. They were filed in the medical record. To the best of my knowledge, Du Pont made no use of the results of the serum antitrypsin [SAT] test. However, the results of the glucose-6-phosphate dehydrogenase (G-6-PD) test, had, in the case of four employees, been used as the basis for reassignment of the four employees from positions in which they had potential for exposure to amino compounds. As indicated in my testimony on October 15, this program was undertaken without the approval of the medical director, and upon discovery of the fact that this test was used as the bases for placement decisions, the plant physicians was advised that such tests should not be used as the basis for placement decisions. To the best of my knowledge, there have been no other such placement decisions and, as I have testified, this test is no longer being conducted.

Mr. GORE. Now, would you describe for the record your knowledge as a physician of the significance for an individual who has an SAT deficiency?

Dr. KARRH. There has been data that indicate that someone with an SAT deficiency is more likely to develop a chronic lung disease, particularly an emphysema-type of condition as a result of this deficiency of enzymes in their body.

Mr. GORE. Shouldn't they have been told, those who had the SAT deficiency?

Dr. KARRH. Those who had the SAT deficiency were told of the results of the test. You asked me earlier if they were notified prior to the test and if they were told of the purpose of the test.

Mr. GORE. I asked you what counseling or educational program was established for employees who were found to have SAT deficiency.

Dr. KARRH. I answered there were no counseling or education programs, but they were advised of the results of the test.

Mr. GORE. Were they told what the significance of the result was?

Dr. KARRH. To my knowledge they were not. They were just told of the results of the test.

Mr. GORE. If a proposal came across your desk today to begin yet another pilot program to investigate a new genetic screening technique, would you handle any differently than you did in the past?

Dr. KARRH. I did not handle any in the past.

Mr. GORE. Let me rephrase it then.

Would you handle it any differently than your company has handled it in the past?

Dr. KARRH. The two tests that were done at the one plant, the SAT and G-6-PD, were not done as a result of anything that came across the medical director's desk.

They were started by a plant physician without sending anything across the medical director's desk, so in that case, I can't answer the question. We now have controls that before any testing like that is done, I have to be consulted prior to initiating the program.

As far as the sickle-cell testing is concerned, we would probably look at it more closely today than we did in 1972 when we were trying to be responsive to the request of employees, and would try to determine exactly what use would be made of this and whether or not it could subsequently be misconstrued by someone who wanted to misconstrue it.

Mr. GORE. Or by someone who, without a desire to misconstrue, picked up an impression that a reasonable-objective observer might be prone to pick up.

Dr. KARRH. There was an opportunity for explanation of that because prior to publication of the article in the New York Times in February of 1980, both Dr. Reinhardt and I talked to the reporter. That question on interpretation was never posed to me, nor was I questioned about what that statement meant and whether or not we used the test in any way for job discrimination.

I am sure that if he had a misconception of that statement, he had as a good reporter would, an obligation to question whether or not he had understood it correctly.

Mr. GORE. Leaving that aside, going back to the question about yet another pilot program, leaving aside the controversy over the sickle-cell trait matter, if you become aware of a physician at one of our plants embarking on another investigation of a new genetic screening technique, would you allow it to proceed as these in the past did, the SAT and the G-6-PD cases did?

Dr. KARRH. He would have to present justification as to why the test was being done and how it would be applied and what was the utility of it as far as our employees in the workplace were concerned.

Mr. GORE. Does the company now have a policy restricting the freedom of plant physicians to embark upon such programs?

Dr. KARRH. We have a policy that they have to clear these with me before they can be started.

Mr. GORE. Your testimony is if one came to you for clearance today, you would handle it differently than the two examples I just cited were handled in the past.

Dr. KARRH. As I mentioned, I did not handle the two in the past, but I would handle it differently than what they apparently were handled.

Mr. GORE. I assume that those differences would include matters of informed consent and counseling and the other matters.

Dr. KARRH. I am sure they would because you have to recognize that society has demanded more in informed consent since these tests were started in the early 1970's. That is true in the private practice of medicine where surgeons have to provide much more informed consent.

Mr. GORE. Would you agree that the present efforts to determine the efficacy of genetic screening were conducted under a cloak of secrecy of sorts?

Dr. KARRH. No, I would not agree. If that were the case, they would not have been in Dr. Reinhardt's article.

Mr. GORE. I want to thank you for bearing with me through this long series of questions and I know you understand, having listened to the earlier statements, that we are quite concerned about trying to learn from these early examples some lessons or princi-

ples that will assist us as a society in the future when such techniques become more commonplace.

Do you agree with my anticipation that such technologies as the HLA antigen screening and others are likely to make this problem or this issue much larger than it now appears?

Dr. KARRH. I would have to disqualify myself on that because I am no expert on genetic screening or genetic testing and I don't think I have enough expertise to answer that question.

Mr. GORE. This is one of a series of hearings and we will be returning to this issue, examining the somewhat different aspects of it later this fall.

This concludes this 2-day set of hearings that are a part of a series and I would like to conclude by thanking all the witnesses who appeared during the hearings and who have helped enormously in our effort to try to develop a better understanding of the issues that are raised.

Thank you all and the hearing is adjourned.

[Whereupon, at 12:55 p.m., the subcommittee was adjourned.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

The New York Times

220 WEST 43 STREET
NEW YORK, N.Y. 10036

October 18, 1981

Congressman Albert Gore
U.S. House of Representatives
Room 819, House Annex #1
Washington, D.C. 20515

OC 18 1981

Dear Mr. Gore:

I covered your hearings on genetic screening in industry on October 14-15 and, as you may know, I wrote the original series on genetic screening for The New York Times which ran February 3, 4, 5 and 6, 1980. I am enclosing a reprint of the original series, in the event you need an extra one for your files.

During the course of the testimony of Dr. Bruce Karrh, the corporate medical director of Du Pont, on October 15, he made some comments about about my reporting of this matter that were, in my opinion, uncalled for. He has made similar comments before.

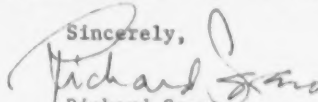
Dr. Karrh suggests that whatever misunderstanding or inconsistencies that may have been created by Dr. Charles F. Reinhardt in his interviews or his 1978 Journal of Occupational Medicine article, vis-a-vis Dr. Karrh's accounts of corporate medical policy, could have been dissipated by Dr. Karrh, if only I had called these things to his attention prior to publication.

I asked very precise questions of both men. There were no trick questions. I feel that it is reasonable to expect them to give competent, lucid answers to such questions, without special coaching. I do not feel that it is the responsibility of journalists to homogenize disparate corporate responses in the interests of their better public image.

In any event, I was invited to give a speech on the aftermath of my genetic screening series last January 8, at the convention of the American Association for the Advancement of Science in Toronto. I am enclosing a copy of that speech, which deals with some of Dr. Karrh's criticisms, and would very much appreciate your including it in the hearing record. I talked to Jim Jensen about it last Friday and he thought it might be an acceptable suggestion.

May I close by saying that I personally appreciate the even-handed way you conducted the hearings. I hope that I will be able to attend any future sessions.

Sincerely,


Richard Severo

Enc.

(289)



School of Public Health, Columbia University
60 Haven Avenue, B-1 New York, N.Y. 10032
(212) 694-3464 or 781-5719

Reprint—1980
from The New York Times
February 3, 4, 5, 6, 1980

Genetic Tests by Industry Raise Questions on Rights of Workers

By RICHARD SEVERO

Petrochemical companies have quietly tested thousands of American workers to determine if any of the genes they were born with are what industry doctors call "defective," making the employees especially vulnerable to certain chemicals in the workplace. The process is called genetic screening.

Employers say the purpose of the tests is to provide a protective barrier, keeping workers they term "hypersusceptible" away from industrial poisons. It is unclear if any workers have been denied employment because of their genes, but there is ample evidence that many workers have been transferred to other jobs.

Some scientists, union leaders and industrial hygienists reject assertions that the tests protect workers. Such critics regard genetic screening as a Brave New World nightmare, an Orwellian stew in which the victims of toxic chemicals will be blamed for having faulty genes.

They say that the genetic approach is indeed a barrier, but one that threatens workers with sexual, racial or ethnic discrimination.

The Genetic Barrier

Job Benefit or Job Bias?

First article of a series.

crimination. They oppose an employment philosophy that would label a particular group of people as unfit for certain jobs because of their genetic makeup. This approach, they say, thus shifts the focus of the problem to the genes of workers, rather than to the presence of industrial poisons in the workplace.

They want industry to place the emphasis on cleaning up the workplace, not deciding which workers ought to be removed from conditions that could ultimately be bad for all.

Whether the companies or their critics are correct, the practice poses enormous moral, legal and ethical questions. It seems likely to add to the debate over the total ramifications of genetic research.

Genetic screening has been going on for years with scant understanding by the public or some of those tested, even though its use has spread from petrochemicals to such industries as steel and batteries.

The process involves drawing a small amount of blood from the worker, no more than would be involved in a routine blood test. A technician then puts this blood through tests that can reveal genetic makeup. The idea is to keep workers with genes that are suspect away from certain chemicals.

But the fear is that the promise could be more than offset by the peril. When used as a pre-employment test, it has the potential for use as a discriminatory tool or as a way to avoid lowering toxic chemical exposure levels. One form of screening called cytogenetics has at least the potential for benefiting workers.

Cytogenetics tests can determine if workers who had "good genes" when they were hired have suffered undue breakage of chromosomes, which are bundles of genes, because of exposure to toxic chemicals. Such breakage is suspected by many scientists to be a harbinger of cancer.

But some scientists say they suspect that companies learn about excessive chromosome breakage and do not tell workers.

Hard Evidence Lacking

At Dow Chemical Company, a company doctor found evidence of undue chromosome breakage among workers exposed to benzene, a widely used chemical and a known carcinogen.

"We wanted them to tell the workers what we had found, reduce the levels of benzene to which workers were exposed and inform the appropriate Government agencies and the rest of the petrochemical industry," Dr. Dante J. Picciano, a Dow geneticist, said. Dow refused, saying Dr. Picciano's data were hard to evaluate and that it would not have been responsible to alarm workers by citing data that might ultimately prove to be inaccurate. Dr. Picciano left Dow.

The New York Times reviewed genetic screening and cytogenetics in the American workplace in a three-month study involving interviews with dozens of scientists, company officials, union leaders and Government policy makers. What emerged was a picture of industrial proponents insisting that the tests are necessary, though there is a lack of irrefutable evidence linking certain genes with documented illnesses in workers.

Proponents emphasize that it is not economically feasible to make the workplace totally safe for all workers and that the tests are not designed to discriminate arbitrarily against minority groups.

It gives the workers a chance to alter their employment goals and enjoy better health, say the proponents. They feel that as tests are perfected and jobs allocated accordingly, the result will be better-protected workers, less absenteeism and a decrease in workers' compensation claims and other negligence litigation, such as that brought for the abnormal children of damaged workers.

Thousands of Workers Tested

And what if a company contends that it cannot clean up a plant? The opponents say that such assertions are specious, that the advanced technology that provides new inventions can also find means to protect everyone from the harmful effects of such inventions. If technology fails to do this, they say, Americans will pay a hidden cost in serious illnesses for themselves and their descendants.

The Du Pont Company and Dow, the principal proponents, say that between them, they have tested thousands of workers over the past decade.

But they did not disclose precise numbers and said they had no systematized data on test results or conclusions about which tests might be better than others. The companies also said they had no

definitive picture of how results are applied in the workplace, and company officials gave conflicting accounts of what they were doing. They said they could not provide specific information on how workers might be benefiting from the tests.

The Times study also found no industrywide definable policy on the protection of confidentiality in employee records and no clearly enunciated attitude of what role, if any, the workers' private physicians should or could play. The companies said they did not know how many workers, if any, were denied the employment of their choice because of alleged genetic unsuitability and given other jobs to preclude their exposure to toxic substances.

Confusing Federal Mandates

There is also a lack of widespread knowledge in industry as to which companies are doing what kind of testing. The extent of genetic screening remains a matter of speculation.

Moreover, there is mystery about the Federal Government's role. A regulation, well known to industry, exists in rules promulgated by the Occupational Safety and Health Administration. To industry, the regulation is a mandate for genetic screening, but many people in OSHA were either unaware of its existence or unable to explain it.

The initial focus of genetic screening involved gene variations associated with sex and race. There are documented instances of women and blacks being barred from jobs as a result of current thinking on hypersusceptibility. General Motors says it will not hire fertile women of child-bearing age to work around lead, even though there is disagreement as to whether lead causes birth defects. The Equal Employment Opportunity Commission says it has about 40 cases of people who contend that they have been barred from jobs because of alleged hypersusceptibility. A spokesman for the agency said that almost all the complainants were women.

It is clear, however, that if genetic screening achieves greater acceptance, the ranks of complainants could swell beyond just blacks and women.

Disorders in Many Groups

The approaches to screening that now raise questions about women and blacks can also lead to questions of the genetic acceptability of certain Italians, Greeks, Yugoslavs, Spaniards, Portuguese, Arabs, Iranians, Jews with roots in the Mediterranean and Middle East, Chinese, Filipinos and East Indians. Some among these peoples, along with American and African blacks, have genetically caused blood disorders such as thalassemia, sickle-cell anemia and a deficiency of the enzyme glucose-6-phosphate dehydrogenase, known as G-6-PD. Basically, all three conditions may manifest themselves as types of anemia.

There are researchers who contend that people with these disorders, or those who may carry only a trait from one parent and thus manifest no symptoms, are at special risk when working with many chemicals. Among them, commonly used in industry, are benzene, nitroamines, nitrates and lead.

Proponents of genetic screening also say that some people with roots in central and northern Europe, among them Swedes, Danes and Norwegians, suffer from an inborn deficiency of serum

alpo, anitrypsin, and are very vulnerable to industrial agents that might trigger chronic bronchitis or emphysema. These assertions, by no means universally accepted, are at the heart of a developing debate over genetic screening.

"Be Tested Because We Can"

Industry spokesmen tend to see the confusion about screening as a consequence that might be expected from new disciplines. They have no doubt that work should go forward.

"As of right now, examining hypersusceptibility in its infancy," said Dr. Paul Kohn, medical director of the Johns-Manville Corporation, "but everybody knows that we are going to continue to live in a world of expanding chemical use. It is all just alarming. Cytogenetics is an idea whose time has come. I think we should do certain tests because we can."

Dr. Kohn concludes that genetic abnormalities represent "only a limited segment of workers at high risk," but he nevertheless feels that industry has a "moral imperative" to study those abnormalities. He also said that Johns-Manville had not yet begun an active cytogenetics program but was watching developments closely.

Genetic investigation to determine suitability for work may be just alarming, but it has already polarized researchers in industry, science, academia and unions.

"A Lot of Victim-Blaming"

The critics tend to see "hypersusceptibility" as a misleading trigger word to describe normal human variation. And they assert that when more sensitive people get sick in the workplace, they should not be regarded as inferior but as the proverbial canaries in the coal mine, manifesting sicknesses that will, in time, touch even the highly resistant workers.

"1984 is already here," said Anthony Mazzamo, director of health and safety for the Oil, Chemical and Atomic Workers International Union. "I think that in the 80's, we are going to see a lot of victim-blaming. The emphasis will be not so much what you work with, it will have to do with who your mother and father were."

Today's genetic screening is more than a simple effort to link at the traits that people may have inherited from their parents. The tests are nothing less than a 20th-century confrontation with human gene pools that were created, defined and reinforced over thousands of generations. They go to the skin of life itself.

They are a manifestation of biochemical problems that were bound to surface with a species, man, whose genetic profile developed some 50,000 years before the Industrial Revolution, over the millennia when life on earth was simple, pastoral, offering nothing more lethal than tribal wars, disease and the poisons encountered naturally in the environment.

Recent Rise of Chemicals

"The thing that disturbs me as a geneticist is that if you see how man has evolved and you look back over the centuries, it is only in the last half-dozen generations that man has come into contact with these new chemicals," said Dr. Neil A. Holtzman, associate professor of pediatrics at the Johns Hopkins Medical School.

Most of the roughly 30,000 chemicals in the marketplace were introduced after World War II, many without extensive testing that would tell for sure what their long-range effect might be. A good proportion of these new chemicals cause gene mutations.

"Essentially, what we're doing is exposing the human gene pool to an environment that is quite different from the environment in which man evolved," Dr. Holtzman said. "We don't know how many of men's genes that predominate today are predominated because of natural selection. Regardless of that number, the fact is that man's genetic constitution did not evolve in an atmosphere filled with the chemicals that fill it today."

Dr. Holtzman said he felt that genetic evolution could never be rapid enough to enable people to be exposed to a continuing array of new chemicals without run-

ning high risks.

The genetic screening and cytogenetics programs in use or under consideration by industry have been developed over the past 15 to 20 years.

In 1963, Dr. Herbert E. Stokinger and John T. Mountain wrote an article in Archives of Environmental Health that is regarded as one of the first significant justifications for genetic screening. The article described a blood test that could purportedly detect a G-6-PD deficiency. It said that a genetic defect was the cause of hypersusceptibility to a certain drug.

The article went on to say: "Although the defect has a low incidence (about 0.1 percent) in white American males, it has a high incidence (about 12 percent) among Negro American males, certain Asiatic Jews, Italian subgroups, Filipinos, Chinese and others. The extension and broader application of this concept to industrial medicine and toxicology is suggested."

Later, Dr. Stokinger became closely identified as a strong advocate of genetic screening. He became chief toxicologist of the Division of Laboratories and Criteria Development of the National Institute for Occupational Safety and Health. He is now retired.

Stress on Clean Workplace

That article, and similar articles by other proponents of genetic screening, are frequently cited by critics as an approach to looking at job applicants that is needlessly ethnocentric, divisive and not central to the problems of the workplace.

"What if you do, in fact, demonstrate that a certain group is more at risk than another subgroup?" asked Dr. Nicholas A. Ashford, associate professor of technology and policy at the Massachusetts Institute of Technology.

"You could eliminate them from those jobs," he said. "Or you could make the workplace safe for everybody, including the most sensitive members of the population. I believe the latter is the only sensible policy."

Dr. Ashford dislikes the "hypersusceptibility" approach and prefers to regard people as having "a biological receptor difference," not one that says genes may be "defective."

Industry Motives Questioned

Dr. Jonathan King, a molecular biologist who is professor of biology at M.I.T., questions the motives of industry in promoting genetic screening.

"From the point of view of the whole work force, it is an extraordinary waste of social resources," he said. "Most of these genetically linked problems are very rare. But the benefits to the company can be immense. Testing switches the focus of the problem from the company to the worker, it gets the company out of having to start a cleanup program. It is a forum of social and intellectual propaganda. It may protect management later on against legal claims, and it deflects attention from the real problem. It costs a lot more to lower cadmium levels than to screen."

Dr. King feels that industry has embarked "on a major effort to deflect the issue" of toxic substances in the workplace and the environment.

"I don't want someone telling me that the chronic anemia I may suffer because of benzene that has been dumped illegally is really because my genes aren't adequate," he said.

Complaints Against Companies

"The allowable level of benzene in the environment should be such that the most sensitive human being does not get sick," he continued. "I have as much right to be healthy as anyone else. But some in industry are saying that because you have less G-6-PD, you do not have the same rights as other Americans to be employed and to be healthy."

Documents from OSHA and the Equal Employment Opportunity Commission examined in November show that there are complaints pending against the Special Chemicals Division of Allied Chemical Corporation of Danville, Ill.; B. F. Goodrich of Avon Lake, Ohio; Avtex Fibers Inc. of Nitro, W. Va.; Environmen-

tal Protection and Airation Systems of Memphis; St. Joe's Minerals of Pittsburgh; various facilities of General Motors, and American Cyanamid-owned plants in Pearl River, N.Y., and Willow Island, W. Va.

All are said to have excluded women of child-bearing age from certain jobs, and the Willow Island case allegedly went much further.

OSHA charged last Oct. 9 that American Cyanamid "adopted a policy which required women employees to be sterilized in order to be eligible to work in those areas of the plant where they would be exposed to certain toxic substances."

The Government ordered the company to pay a \$10,000 fine.

Sterilization as Policy

American Cyanamid says it was "surprised and shocked" at the charge, which it called "absolutely false," and said it would challenge the case "with all the resources at its command."

Reports of women having themselves sterilized so they could continue to work were not new. What was new was that the company had allegedly made sterilization a formal part of employment policy.

Women with such complaints say that the toxic substances frequently cited as being most damaging to females are just as damaging to males.

Among the substances cited by the companies as being especially harmful to women are vinyl chloride, carbon disulfide and lead.

Focus on Lead

But current medical literature says that vinyl chloride is a cancer-causing agent that does not make sexual distinctions; carbon disulfide is known to cause brain damage and harm to the liver and kidneys in both men and women; and lead seems equally toxic to everyone.

Dr. Jeanne M. Stellman, executive director of the Women's Occupational Health Resource Center at Columbia University, says she finds it ironic that so much debate should be conducted on lead's teratogenic, or birth-deforming, effects when "the clinical and subclinical effects on all humans have been well established."

She notes that lead can have severe effects on the nervous system, can cause teeth to fall out and have harmful effects on the heart and kidneys.

"But as for transplacental effects," she said, "it's not even clear what the relationship is between the mother's blood level and the blood level of the fetus or the embryo. There is not one clear-cut experiment establishing that lead is a teratogen."

Effects on Women

"If it is going to be the policy of this society to ban fertile women from working with teratogens," she added, "let's not talk about it with lead — let's talk about it with X-rays. We know X-rays have a tremendous teratogenic effect. I haven't heard anyone suggest that we eliminate all fertile women from the health-care industry where they can be exposed to radiation."

Dr. Stellman's research convinces her that sperm is at least as susceptible to environmental hazards as the ovum and that industry's inability to concede this possibility suggests that it wants to keep women out of the workplace.

"I absolutely resent that if you look at a 14- to 45-year-old woman, you are looking at a woman who is presumed pregnant until proven otherwise," she said. "Sociologically, demographically, it's just not true. Most child-bearing in our society is planned. Ninety-five percent of all women have absolutely finished bearing children by the time they are 35."

"The thrust of this isn't to get women back into the fields and bearing children out of rice paddies," she said. "It is to allow women to work, just as men do."

THE NEW YORK TIMES,
SUNDAY, FEBRUARY 3, 1980

Screening of Blacks by Du Pont Sharpens Debate on Gene Tests

By RICHARD SEVERO

The Du Pont Company, the 13th largest employer in the United States, routinely gives pre-employment blood tests to all blacks who apply for jobs to determine who might be a carrier of the trait for sickle-cell anemia, even though the trait is regarded as largely harmless.

Although there are other genetically transmitted blood diseases and metabolic disorders that predominate in other racial or ethnic groups, blacks are the only ones to be identified with a disease and examined for it at Du Pont.

In a three-month study of genetic

Du Pont's Haskell Laboratory for Toxicology and Industrial Medicine in Newark, Del., said the tests were started in 1972 because a group of black employees at the Deepwater plant asked for them.

In contrast, Dr. Karrh said the requests had come not from the Deepwater plant but from blacks employed in Wilmington, Del. He could not recall who they were. A company public relations representative was unable to supply their identities because, he said, the company never kept a list of those blacks.

"It was not a formal situation," said the spokesman.

Discrepancy on Test Uses

The two officials, who were interviewed separately, also disagreed on how the sickle trait tests were used. Dr. Karrh said that no job-placement decisions were made on the basis of the tests. Dr. Reinhardt said that under certain circumstances, the tests would definitely influence the employment process.

In a 1978 article in *The Journal of Occupational Medicine*, Dr. Reinhardt explained his standard for levels of hemoglobin, the oxygen-carrying pigment in blood. He wrote that, at the Deepwater plant, employees with sickle trait who had hemoglobin counts of less than 14 grams per 100 milliliters of blood "are restricted from work involving the handling of nitro and amino compounds; if their hemoglobin is greater than 14 grams, no restrictions are made."

"We generally employ individuals with sickle-cell trait who appear otherwise able to fill job requirements," he said. His confirmed this in an interview.

But Dr. Karrh said the test, which Du Pont offers nationally to all prospective black workers, was "purely for the education and edification of the individual involved." He said the test was designed "only to advise them. It won't be used in management decisions as far as placement is concerned."

William J. Golt, president of the Chemical Workers Association, a union at the Deepwater plant that is not affiliated with any national union, could offer little information to clear up the discrepancy.

Mr. Golt was aware of the sickle trait test, said he knew of at least one black transferred to another job because of the test, and added that his union generally regarded the test as good. Mr. Golt also said that he had heard that blacks and people of Mediterranean ancestry had special blood problems but that his impression was that they did not get any sicker of the job than anyone else.

Dr. Karrh emphasized that, although the sickle trait test was included with all other tests that were mandatory before an applicant received a job, a black could refuse to take it and still be considered for employment.

"If they did refuse, the plant physician would explain to them that it was being done not for us but for them, and from Du Pont's standpoint, we really didn't care what the results were," Dr. Karrh said. "If they still refused, we probably would not do this particular test. But as far as I know, we've never had a refusal."

After numerous interviews with company officials, it remains difficult to determine precisely what is happening with genetic screening at Du Pont.

Data in Job Records

Dr. Karrh and Dr. Reinhardt said, for example, that they did not know how many blacks had been screened since the program was started in 1972 or how many instances of sickle trait had been found, and that they had derived no systematized data from the tests. Dr. Karrh said the test results that might yield data were included in the employment records of black workers "and it would be quite a big task to pull that together."

Proponents of genetic screening have suggested that carriers of a sickle-cell

gene might be at increased risk if they are exposed to a group of chemicals regarded as "hemolytic," that is, causing the destruction of red blood cells.

It is known that a very small number of the people with sickle trait may experience some of the symptoms of sickle-cell anemia under extreme conditions of oxygen deprivation. The theory, by no means universally accepted, is that their exposure to some chemicals used in the workplace might also set off a "sickling" incident in which red blood cells become sickle-shaped and thus unable to carry needed oxygen.

But the same theorists also suspect that carriers of the thalassemia gene or people with G-6-PD deficiency run similar or even greater risks in the chemical industry. It is not clear why carriers of sickle trait require a scrutiny that apparently is not regarded as necessary for those who may have thalassemia or G-6-PD deficiency.

Hemoglobin Standard

Moreover, there is a debate among researchers about the science underlying the sickle-trait screening.

Dr. Reinhardt said that 14 grams represented an "upper normal range of hemoglobin" so that, even if a person worked with chemicals regarded as destructive of red blood cells, he would not be at risk, even if he somehow ingested small amounts of the chemical. But below 14, he said, workers would be "at somewhat greater risk."

Dr. Reinhardt added that there was "nothing magic about the number" but it was the one Du Pont was working with.

"At Du Pont," he said, "we have no formal stated policy on particular types of hypersusceptibility but do consider all known pertinent factors and their combined effect in a particular situation. Our approach is individualized, strictly practical."

Tests Rejected at Shell

Many geneticists, scholars and physicians, in and out of industry, have reservations about the Du Pont approach.

Dr. Roy F. Joyner, medical director for the Shell Oil Company, said that Shell did not conduct any pre-employment genetic screening and had no intention of following Du Pont's example.

"I don't think the evidence is conclusive that the screening is worthwhile," Dr. Joyner said. "If you do it as part of pre-employment testing, you may be denying employment to someone on the basis of something, that is at present only a research tool. It does not have the validity to be used on a mass basis."

Dr. Marvin S. Legator, a researcher in genetic toxicology at the University of Texas, said that "for every sickle-cell trait they can identify, we must have 1,000 more heterozygote carriers for diseases that we can't identify. Testing for sickle-cell trait is a pittance. It shows abysmal ignorance to try to identify only that group in the population when there are so many others. It is almost irrelevant, and many of us fear that such tests may be used as a gimmick not to clear up the workplace."

Dr. Barton Childs, professor of pediatrics at the Johns Hopkins Medical School, said he could see no reason for the Du Pont screening program for sickle trait.

Dr. Childs was chairman of the Committee for the Study of Inborn Errors of Metabolism that was organized five years ago by the National Academy of Sciences. It examined genetic screening, including sickle tests.

Dr. Childs said that he could attach no particular scientific significance to Dr. Reinhardt's 14-gram hemoglobin level and added that he could not conceive of any workplace conforming to minimal hygienic standards that would pose a problem to anyone with sickle trait.

A 388-page book prepared by Dr. Childs' committee warned of senseless stigmatization of sickle trait carriers.

Insurance Rates Affected

"Evidence of stigmatization in the United States is seen in job discrimination, in proposals to limit admission to the armed forces to noncarriers, and in increases in insurance premiums," the book said. "Nine of 12 insurance compa-

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screening in the American workplace. The New York Times found no other instance of an ethnic or racial group singled out in a major company as blacks are at E. I. du Pont de Nemours & Company.

Du Pont officials emphasize that the sickle trait tests do not represent discrimination against blacks and are only an effort to help them avoid potentially harmful exposure to certain chemicals. Yet the officials can offer no firm evidence that the trait—not the disease, but only a single abnormal gene—makes blacks more vulnerable.

Du Pont, which employs well over 100,000 workers, is in the vanguard of American companies doing genetic screening and thus is at the center of the debate over this area of science. It is a debate so intense, so broad, that even medical directors from other companies who believe in the possibilities of genetic screening want no part of it. At least, not now.

But officials at Du Pont, a leader in the chemical industry with annual gross sales of more than \$10 billion, feel they have the money and the scientists to turn the distrust into achievement.

If some chemicals are highly toxic and the workplace is less than pristine, reason company officials, it is only logical to try to determine why some workers get sicker faster and others seem to have more tolerance for industrial poisons. And so the company is looking beyond the skills and loyalty of its workers to their very genetic structure.

Sickle-cell trait is not the same as sickle-cell anemia. The anemia is a rare but debilitating disorder found in fewer than 50,000 American blacks, about two-tenths of a percent of the black population.

Perhaps two million other blacks are carriers of the trait—they are heterozygous; that is, having a gene for sickle-cell anemia from one parent. Virtually all the carriers can lead very active lives and show no symptoms of the disease.

Other Illnesses Cited

While Mediterraneans share the sickle problem with blacks, although its incidence is extremely rare among whites. Both peoples are also subject to thalassemia and to a deficiency of the enzyme glucose-6-phosphate dehydrogenase, called G-6-PD. Basically they are kinds of anemia that researchers agree surpass sickle trait as a health risk.

Dr. Bruce Karrh, Du Pont's medical director, estimates that people with Italian surnames are the largest single ethnic group employed at Du Pont's biggest chemical plant, at Deepwater, N.J. Yet, even there, only blacks receive special attention in the genetic screening process.

Company officials gave confusing and conflicting accounts of how the tests began and of their perceived value.

Dr. Charles F. Reinhardt, director of

ries in one sample charged higher rates for individuals with sickle trait even though mortality curves for such individuals do not differ significantly from blacks without the trait.

Dr. Robert F. Murray Jr., a Howard University geneticist who served on Dr. Childs' committee, wondered why Du Pont's stated concern about the 14-gram hemoglobin level was limited to those with sickle trait.

He noted that white Mediterraneans who have thalassemia trait sometimes suffer from mild anemia, so that their hemoglobin might fall below 14. "If Du Pont is really concerned about the 14-gram level, then they ought to be screening for thalassemia," he said. He noted that although thalassemia sometimes occurred among blacks, this variety tended not to have anemia associated with it.

Du Pont's Dr. Karrh said that no thought had been given to testing for thalassemia trait or the actual disease.

Nor has Du Pont given any thought to checking white workers of Mediterranean ancestry, as a group, for their genetically linked blood diseases.

'How We Observe People'

Dr. Karrh said that such a test "would be interesting and very well could be productive — right now, I don't know what we would anticipate getting out of it, but it's something we could consider."

The company tests occasionally for G-6-PD deficiency, which occurs among blacks and white Mediterraneans. Du Pont has not linked the problem with any ethnic or racial group for test purposes.

The Deepwater plant is the only place where the test is done routinely by Du Pont; elsewhere it is at the discretion of company medical personnel. As with the test for sickle trait, there are no data yet linking those with a deficiency to illness in the workplace. "The test is not used for job placement," Dr. Karrh said. "It's a test we are using as a predictive tool, and it is also how we observe people."

Du Pont's critics say there are no hard scientific data to suggest that either white Mediterraneans or blacks should be subjected to special tests for genetic problems. They object strenuously to the fact that, in the sickle trait test, Du Pont has a national program for blacks only.

"This policy of Du Pont's is very clearly a eugenic policy," said Dr. Jonathan King, a molecular biologist at the Massachusetts Institute of Technology. "There is no evidence that heterozygotes for sickle trait are substantially more sensitive than other people. Du Pont's position is scientific racism. They say they are not bigots because all this is based on science. But the fact is that people are not going to get sick because they are hypersusceptible, they are going to get sick because they are being poisoned."

From Du Pont's view, the test for sickle trait is nothing more than a part of the company's total effort to give occupational health a new and more meaningful dimension.

Dr. Karrh noted that Du Pont also conducted a pre-employment test to determine if the applicant has a deficiency of serum alpha₁ antitrypsin, which is suspected by some researchers as a precursor of emphysema and chronic bronchitis. The test is done routinely only at the plant at Deepwater.

Dr. Karrh regards the alpha₁ antitrypsin program "as a sort of pilot project to see if it is a good predictive tool for people who will subsequently develop pulmonary disease."

Deficiency Is Rare

Alpha₁ antitrypsin deficiency is rare. In 1976, a group of Canadian researchers estimated that a "pronounced deficiency" of it occurs in at least one of 7,400 North Americans and one in 1,750 Swedes. People of Danish and Norwegian ancestry are believed to have the deficiency as frequently as do Swedes, and medical research shows that it has occurred less frequently among the Irish, English and Germans.

At Du Pont, no effort has been made to isolate ethnic groups suffering from the deficiency with the most frequency. Some scientific researchers feel that there is extremely limited value in look-

ing for alpha₁ antitrypsin deficiency.

In 1976, for example, Dr. James O. Morse said in the *New England Journal of Medicine* that "in view of the limited prevalence of severe deficiency, it is doubtful whether a program to screen the general population for this defect would be worthwhile." He added that he doubted that such testing would be useful even for "workers who might be exposed to occupational air pollution."

Dr. Karrh said that somewhere between 500 and 1,000 prospective employees had been given the alpha₁ antitrypsin deficiency test at Deepwater, and that probably less than 10 had been found with the deficiency.

Dispute Arises Over Dow Studies On Genetic Damage in Workers

By RICHARD SEVERO

Special to The New York Times

HOUSTON — In the mid-1960's, Dr. D. Jack Kilian, medical director of the Dow Chemical Company's huge production facilities in Freeport, Tex., began to conduct experiments in cytogenetics, a branch of genetics that focuses on changes in chromosomes.

Dr. Kilian was one of the researchers who believed that undue changes in chromosomes, the rod-shaped bodies that contain genes, might be a harbinger of cancer and birth defects.

He began to study such changes, noting the differences between workers exposed to highly toxic chemicals at Dow and those not yet exposed — those who were only applying for work. By the mid-70's, he became convinced that if any worker consistently showed a high rate of broken chromosomes, it was ample cause for concern.

Transfer of Workers

Dr. Kilian sought the formulation of a new company policy under which workers showing such mutation would be noti-

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fied candidly, then transferred away from the chemicals that might be the cause of their trouble.

But such a policy was never promulgated, and Dr. Kilian left the company a disappointed man. The key people who worked with him are gone, too.

Dr. Kilian, who quit Dow to become a professor at the University of Texas School of Public Health, said that when his cytogenetic research seemed to suggest that Dow's production methods were clean and safe, as his work on vinyl chloride had shown, the company happily let him publicize his findings.

But when he and his associates found that workers exposed to benzene and epichlorohydrin were suffering a disturbing rate of chromosome breakage, he said, company officials grew distant, hostile and defensive about the studies.

Dow now expresses strong reservations about the quality of laboratory work by Dr. Kilian and his associates.

While he was at Dow, Dr. Kilian's approach to dealing with workers showing chromosome breakage was markedly different from the approach of E. I. du Pont de Nemours & Company, where genetic screening dealt with gene abnormalities that were sex-linked or associated with race or ethnic background.

The differences were regarded as so significant that, at Dow, cytogenetics was never referred to as genetic screening, although in reality it was only a variation on a theme of that science.

Dr. Karrh was asked if he felt the test might have an uncertain future in terms of cost and benefit.

"Yes," he said. "We've wondered about it ever since we started it." The tests will continue, however, until the company makes a final determination as to its value, he said. He did not know when that would be.

THE NEW YORK TIMES,
MONDAY, FEBRUARY 4, 1980

Cytogenetics was something special. It was not to be used to screen job applicants out of the workplace. In Dr. Kilian's approach, everyone's chromosomes should be watched, not just those of blacks or women or others whom some researchers had singled out for alleged "hypersusceptibility" to certain chemicals.

'Brave New World' Twist

Some elements of traditional genetic screening were also being used at Dow, such as the test for a deficiency of the enzyme glucose-6-phosphate dehydrogenase, or G-6-PD, which may manifest itself as a form of anemia. But Dr. Kilian was convinced that his approach to cytogenetics would prove to be much more effective in protecting both the workers and the company's stated interest in having a safe and healthy workplace.

It was, in short, a benign twist on the plot of Aldous Huxley's 1932 novel, "Brave New World," in which workers were "trained" to tolerate toxic chemicals. In Dow's version, as envisioned by Dr. Kilian, workers would not be trained to tolerate such chemicals but removed from them, if there was evidence of chromosome damage. Those who showed no genetic damage would remain in the workplace, continuing their exposure to toxic substances.

As the 1980's begin, Dr. Kilian remains convinced that cytogenetics can still be used to protect workers, but he is not so sure that the principles he pioneered will ever be embraced by industry.

As for Dow, it concedes that after more than a decade and a half of cytogenetic research, said by Dr. Kilian to involve thousands of workers, the company has no idea of precisely how many were screened, what the tests really showed, what the successes and failures were and how Dow might use cytogenetics to make the chemical workplace safer.

Back to Square One

Dow, the nation's principal industrial cytogenetics researcher, says that despite all its efforts, it still has no real data. The company says it has returned to the level of inquiry that existed at the beginning of its cytogenetics research and is trying to determine if it is possible to perceive early indicators of chemical toxicity in the chromosomes of workers.

Dr. John R. Venable, who succeeded Dr. Kilian as medical director of Dow's Texas Division and who has recently been promoted to director of medical and biomedical research for Dow Chemical in the United States, says that the company regards its cytogenetic research as important as ever.

The company's reservations about work done under Dr. Kilian, he said, concerned the quality of the experiments and the controls used.

As a result, Dr. Venable said, Dow has no alternative but to start the research from the beginning, looking first at office workers who had not been exposed to toxic chemicals. The protocol, or format,

for the new research may be ready in the coming year.

In an effort to learn what happened to cytogenetics at Dow, *The New York Times* interviewed past and present employees of the company's Texas Division, as well as various professionals who acted as consultants.

There was considerable reluctance to talk unless identities were concealed. With Dr. Kilian's departure, cytogenetics has become a sensitive subject at Dow, and some of those approached for opinions said they feared the company would somehow impair their future chances to find work in the chemical industry if they were openly critical.

What emerged from their perceptions is a program surrounded by uncertainty, rumor, even mystery in an industry that has become sensitive about what it sees as a poor public image.

Dr. Marvin Legator, a former Dow consultant who is director of the Division of Environmental Toxicology at the University of Texas Medical School, makes no secret of his disapproval of the way Dow has backed away from Dr. Kilian's work.

Holding Company Accountable

"It would seem to me," Dr. Legator said, "that from a moral and legal standpoint, industry should be held accountable for not doing these procedures and informing their workers. They should be held liable for having the procedures and not using them to protect the workers."

Does Dow really have the procedures?

Dr. Dante J. Picciano, a geneticist who worked in Dow's Texas Division under Dr. Kilian, thinks that the company's cytogenetic technology is very good but not put to much practical use. As an example, he cited his own work at Dow.

In June 1977, he said, he told his superiors that he had studied 52 workers who had been exposed to fairly low levels of benzene, a highly toxic chemical widely used in the production of plastic, pharmaceuticals, pesticides and other products.

Dr. Picciano was mindful that benzene was a carcinogen, and he was alarmed at the elevated rate of chromosome breakage he had found.

Company Doctor Thwarted

"They started dragging their feet," Dr. Picciano said. "We wanted them to tell the workers what we had found, reduce the levels of benzene to which workers were exposed and inform the appropriate government agencies and the rest of the petrochemical industry."

Dr. Picciano says his request was not granted. Indeed, he says his fortunes at the company changed as soon as he found cytogenetic evidence that he interpreted as meaning that some workers were suffering undue chromosome breakage because of exposure to certain chemicals.

"As soon as I got positive results," he said, "everything turned against me, and at no time did anybody ever say to me, 'What are we going to do about the workers?'"

Dr. Picciano quit Dow and is now director of the Genetic Toxicology Center, a consulting firm in Vienna, Va.

Problem of Evaluation

In the subsequent fuss over Dr. Picciano's findings, Dow took the position that the data he produced were difficult to evaluate and that it would not have been responsible to alarm workers by citing data that might prove to be inaccurate.

Dr. Venable said that some of the previous work by Dr. Kilian and Dr. Picciano did not take into proper account such factors as the viruses workers might have had, medication they might have been using, laboratory test techniques and even the season of the year. "There is undoubtedly a seasonal variation in chromosome breakage," he said.

Dr. Venable would not comment directly on the departure of Dr. Kilian and Dr. Picciano and their criticism of the company. He confined his comments to evaluating their science, calling their alleged lack of proper laboratory controls "a bad mistake." He said Dow had hired medical consultants to check their work.

"We sure ought to have some answers," he added, "and we don't have all the answers we really need. Our activi-

ties right now are devoted to finding out what the variables are and how they affect the chromosomes."

Study of Office Workers

Dr. Venable says the company cannot accurately evaluate chromosome breakage among production workers until it conducts a lengthy chromosome study of its office workers who have not been exposed to chemicals in the workplace.

Apparently, the Dow Chemical Company has decided to reinvent the wheel, said Dr. Picciano, when told of the company's plans. "Testing office workers to define normal chromosome breakage is like growing peas to see if Mendel's laws were correct."

Moreover, Dr. Picciano said that he saw an inconsistency in Dow's policy.

"In the vinyl chloride study, no bad effects were found on workers," he said. "Dow not only allowed us to publish our findings, but let us go around the country beating our own drum. Nobody suggested then that the controls were off or that office workers had to be tested first."

Doubt on Laboratory Method

Dr. Kilian pointed out that in his study of epichlorohydrin, a solvent used in paints and varnishes, he found a doubling of the chromosome breakage rate in production workers as compared with the control group, job applicants tested in pre-employment screening.

"Yes, there may have been differences because of the laboratory methods used," Dr. Kilian said. "But the control group was run with the same methods and the study was still positive."

Not all former members of the Kilian team totally agree with him.

Dr. Betty Dabney, a biochemist and molecular geneticist who worked for Dr. Kilian, and who also quit the company, said she felt that the cytogenetics effort lacked a system of checks and balances and that some laboratory variables "weren't properly controlled."

Uncertainty on Cancer Link

Dr. Dabney also does not support Dr. Picciano's position that workers with a consistently high number of broken chromosomes ought to be told about it.

"Some people with high levels of broken chromosomes are clinically normal 30 years later," she said, "and it just hasn't been proven that broken chromo-

somes mean cancer. We cannot tell a person with broken chromosomes that he is going to get cancer. So what do we tell them? We need to do more work."

Dr. Picciano agreed that more work was needed, but he took sharp issue with Dr. Dabney's suggestion that people who have had high levels of chromosome breakage for 30 years have no health problems as a result.

"To the best of my knowledge nobody has ever developed information of that sort," he said. "That's exactly the type of information we need. Nobody has followed people for 30 years. But the correlation with people who have elevated levels of chromosome breakage and groups that develop cancer is just overwhelming."

Lower Exposure Advocated

Dr. Picciano was asked what he thought the workers at Dow could have been properly told by the company.

"I would have told them, 'Look, you have an increased level of chromosome damage. If it's persistent, it means you have a higher risk of cancer, higher risk of having children with birth defects and a higher risk of spontaneous abortions.' I think we have an ethical responsibility to tell them to avoid exposure to the chemical they've been working with, and I think the chemical company must move to lower the exposures."

Though Dr. Dabney supports some positions taken by Dow, she has no regrets about leaving the company.

Asked why she left, she said she felt that she did not have the freedom she needed to do sound research. And, she said, company officials tended to view her as being in Dr. Kilian's camp, even though she did not always agree with him.

However, Dr. Dabney added that she still believed that Dow "is one of the most responsible companies in the area of occupational health, controlling environmental pollution and putting out a good quality product."

THE NEW YORK TIMES,
TUESDAY, FEBRUARY 3, 1980

Federal Mandate for Gene Tests Disturbs U.S. Job Safety Official

By RICHARD SEVERO

The head of the Federal agency responsible for the health and safety of American workers has expressed surprise and concern that a Government regulation mandating genetic screening in industry has been in effect for six years without the knowledge of key Government officials or their advisers.

The Federal rule is known to many industry advocates of industrial genetic screening. But Dr. Eula Bingham, director of the Occupational Safety and Health Administration since 1977, said she was unaware of the regulation until told about it last Friday by *The New York Times*.

"I'm just astounded that it's there," she said, "and I will ask our lawyers to

She indicated yesterday that industry proponents of genetic screening might have gone too far and used genetic testing "to place the burden of controlling toxic substances on individuals who are denied employment because of their supposed sensitivity, rather than on companies who should be cleaning up the workplace for all."

The situation at the agency provides an illustration of the tangled state of genetic screening. Even to experts who have studied it, the science remains surrounded by uncertainty over what it has accomplished, confusion over where it is now and fear about where it might go tomorrow.

Key people in government and science were unaware of the Federal mandate's existence, had no idea how it got into the rules and, like Dr. Bingham, could not explain what it meant.

She emphasized that she was not opposed to all forms of genetic screening but wanted to make sure that it was not being abused.

Some in industry view the screening test as a way to find people who are vulnerable and remove them from potentially harmful work areas. But critics

The Genetic Barrier

Job Benefit or Job Bias?

Last of four articles.

study it. We'll either have to interpret it so that we may issue field directives, or take it out of the regulations altogether. In any event, it should not be used as an exclusionary tool against any group of people by industry."

content that an uncertain science has become misleading and arbitrary, giving undue attention to matters of race, sex and ethnicity.

Moreover, some researchers in and out of industry have questioned the science on which screening is based, suggesting that the evidence is not sufficient to link the genetic traits of workers with vulnerability to industrial poisons.

The mysterious OSHA rule is contained in Part 1910, Title 29, of the Code of Federal Regulations, promulgated for general industry by the agency.

Advisory Committee Surprised

A section entitled "Medical Surveillance" says that workers are to take a "preassignment physical examination," which is to include "the personal history of the employee, family and occupational background, including genetic and environmental factors." Unlike much of the terminology in the regulations, the word "genetic" is not defined.

Dr. Bingham said she wondered how it got there.

Even members of the advisory committee that assisted in the creation of the regulations on cancer-causing chemicals, when told recently about the genetic mandate, said they had not known that it existed or what it really meant.

"I personally don't recall any mention of genetics in our deliberations," said Dr. Samuel Epstein, an advisory committee member who is a professor of occupational and environmental medicine at the University of Illinois School of Public Health. "Please don't in any way equate the regulations with the wishes of the independent scientific community or the committee."

"Blame-the-Victim Strategy"

He added: "Had I been shown the word, I would not have agreed to it, for it creates a potential for mischievous ambiguity. I regard the use of the word 'genetic' in this instance as an open sesame for industry to say, 'Aha! Let's use that as an essential element in our blame-the-victim strategy.'"

Another scientist who served on the committee was Dr. Jeanne M. Stellman, executive director of the Women's Occupational Health Resource Center at Columbia University.

She also could not recall any committee discussion about genetic screening and blamed the confusion on Catch-22.

"If industry doesn't do genetic screening of some sort, they are apparently in noncompliance with the law as it now stands," said Dr. Stellman, "but if they try to come into compliance, the law hasn't defined for them what it is they are supposed to do."

The Du Pont Company routinely conducts pre-employment screening of all blacks as "sickle trait," even though leading medical authorities regard the trait as largely harmless.

Sickle trait simply refers to the inheritance of a sickle gene from one parent. It is not the same as sickle-cell anemia, a debilitating disease that occurs when the gene is inherited from both parents.

Dr. Bingham said she found it "unbelievable" that Du Pont was screening blacks. Du Pont's medical officials have given conflicting accounts of what the screening was for, but they agreed that it benefited black workers. They have not specified the benefits.

In a letter yesterday to The New York Times, Irving S. Shapiro, Du Pont's chairman, reaffirmed that the tests were for the benefit of workers and denied that they constituted discrimination.

OSHA is not the only Federal agency with an interest in genetic screening.

The Equal Employment Opportunity Commission voiced concern, in a 1978 statement, that employers "have at times undertaken employment practices or policies that adversely affect the economic opportunities of women of child-bearing capacity and others" by "excluding them from jobs involving exposure to allegedly hazardous substances."

The commission has indicated that such screening from the workplace is a violation of the Civil Rights Act of 1964.

The commission also has about 40 cases of women charging such discrimination. No action has been taken, though the

cases have been pending for many months.

New Suggestions for Society

A commission spokesman said the delay was because the cases had been filed when a cumbersome review procedure was in effect. He said that new cases would be disposed of in a new review system that would take no more than 80 days. It is not possible to place the old cases in the new review system, he added.

While some scientists in academia believe that genetic screening has limited usefulness, other researchers have broadened their own approaches to the science by offering new suggestions as to what society should do with people said to be "hypersusceptible."

Dr. Edward J. Calabrese, a physiologist at the University of Massachusetts, is a leading researcher into the possible hazards faced by individuals who have a deficiency of the enzyme glucose-6-phosphate dehydrogenase, known as G-6-PD.

In his 1978 book, "Pollutants and High Risk Groups," Dr. Calabrese noted that people with G-6-PD deficiency are a source of concern if they live in "high ozone" cities such as Los Angeles, Philadelphia and Chicago.

"Pollution-Free Zones"

"The idea of moving to a new and relatively unpolluted area would certainly be a valuable option, especially for those individuals in various high-risk groups," he said. "With this in mind, the idea of pollution-free zones for high-risk groups should be considered."

Dr. Richard D. Stewart of the Medical College of Wisconsin, writing in The Journal of Occupational Medicine in 1978, addressed the auto pollution problem by suggesting that "suitable artificial environments" be provided for "those individuals who are adversely affected by low concentrations of carbon monoxide."

Dr. John H. Weisburger, vice president for research of the American Health Foundation in New York, suggested in 1977 that perhaps one way to avoid problems caused by work with cancer-causing substances was to hire older people.

"We should consider dosage and time together when selecting individuals where exposure to carcinogens might occur," he wrote in Chemtech, the magazine of the American Chemical Society. "In older persons, low total doses would be possible over the remaining years of employment since the total lifespan for cancer development would be limited."

Stress on Diet Suggested

The man regarded as the father of genetic screening, Dr. Herbert E. Stokinger, says even the diet can play a role in protecting workers against cancer-causing chemicals.

Dr. Stokinger recently retired as chief of the toxicology branch of the Division of Laboratories and Criteria Development of the National Institute for Occupational Safety and Health. He has also been chairman of or served as a member of more than a dozen key national committees dealing with setting standards for various toxic substances. He was interviewed at his home in Cincinnati.

Dr. Stokinger said he believed that chemical workers, whatever their genetic or chromosomal condition, could protect themselves against the bad effects of vinyl chloride — an undisputed human carcinogen — by eating onions, garlic, brussels sprouts, cabbage, broccoli and turnips.

"Yellow turnips are better than white ones," he said.

A number of scientists said they did not agree with Dr. Stokinger's theory on the effects of such brassicae vegetables.

"It rings no bells whatsoever," said Dr. Jessica Davis, a geneticist at Cornell.

Other scientists gave similar responses. Dr. Stokinger, like some other proponents of genetic screening and cytogenetics, feels strongly that the screening has not been given a fair chance.

Dr. Stokinger attributes much of the controversy over screening to the "ultra-conservative American physician," who, in his opinion, ignores indicators that more genetic testing is needed because he is "fearful of labor union confrontations."

"There is little doubt in my mind that the 1980's will be an era of genetic confrontation," said Anthony Mazzuchi, director of health and safety for the Oil, Chemical and Atomic Workers International Union.

"People Will See the Damage"

"I think we are going to see for the first time the results of the last 30 years' work in petrochemical and other industries, and we will start to associate abnormal children with the work their parents did," he added.

"Workers are going to find out that because of their labor, the children they worked for and hoped would have a better life, will instead have abnormalities. There never has been an era like the 80's will be. People will see the damage that has been done."

Accompanying the confusion over genetic screening are suspicions about industry's motives for it.

Even some proponents of certain kinds of genetic screening, like Dr. Dante J. Picciano, a former consultant to Dow, are fearful that what he sees as industry's lack of responsiveness and ethical concern may cause a reaction against the tests and thus obscure the good that can come of them.

"I think that cytogenetics can and should come into wide use," said Dr. Picciano, who quit Dow and charged the company with ignoring research indicating that some workers had been damaged. "I think we ought to look for mutagenic substances" — those that cause gene variations — "but when we find people who have been so changed, we should not just move them out and replace them with fresh workers. We should go in and clean up the workplace so that anybody can work there. There is no other choice."

But in wide areas of academia, there is a feeling that most industrial researchers do not share Dr. Picciano's view. As a result, some scientists say they feel that genetic screening in its present state of development has no use at all in the American workplace.

"There is no convincing evidence that tests can be performed on workers which will accurately predict who will be sickened on the job and who will not," said Dr. Stellman.

"It makes no sense to set testing rules," she said, "until we establish that the tests have validity."

Dr. Nicholas A. Ashford, associate professor of technology and policy at the Massachusetts Institute of Technology and chairman of the National Advisory Committee on Occupational Safety and Health, agrees.

"The opportunities for possible abuse by management present a socially unacceptable risk," he said. "It would be foolish to let management do the testing without legally guaranteeing full disclosure to the worker, a job at equal pay within the firm, and an aggressive policy of job redesign by management and labor to provide a reasonable number of places for these workers within the firm."

"From a social policy perspective we may be focusing on the wrong pathology in addressing genetic factors," said Dr. Ashford. "The most serious pathology is misguided industrial practice. Perhaps we should find a way to screen out firms that are especially susceptible to unfair and unethical practices."

THE NEW YORK TIMES,
WEDNESDAY, FEBRUARY 4, 1980

GENETIC SCREENING AT DU PONT;
EDITORIAL WRITING AT THE WASHINGTON POST

Remarks by Richard Severo
Prepared for delivery to the
American Association
for the Advancement of Science
Toronto, Canada
January 8, 1981

My remarks will concern themselves with the way genetic screening may or may not be practiced at the Du Font Company and the way editorials may or may not be written at The Washington Post. I hope that my subject does not sound too vague to you, but I suspect that many of you -- at least those of you who do not work for Du Font or The Washington Post -- may come to share my concern at the facts that I am about to present to you. I wish to make clear that I am not suggesting that this is the way business is usually done at either Du Font or The Washington Post. Nor am I saying that these two companies are representative of what happens in the interface between the chemical industry and American journalism. Rather, this is a case study of a double misadventure. I present it to you because, it seems to me, it represents a good example of non-communication.

2.

For there was non-communication between Du Pont and its workers, between Du Pont and the public, and between Du Pont and The Washington Post. Apparently, there was also non-communication between a Washington Post editorial writer and her editors and surely between the same editorial writer and her readers.

I have been told that my presentation should be as brief as possible. I will try to comply, but some background detail is necessary if you are to understand precisely what happened.

For that reason, we must go back to May 16, 1972, when President Nixon signed \$115 million worth of legislation that promised intensified efforts to find a "cure" for sickle-cell anemia and to provide new assistance for its victims, most of them black. The Nixon Administration had been expressing interest in the sickle-cell anemia problem for the better part of a year in what was, at least in part, an effort to persuade a wary black community that the Government was really interested in its problems.

3.

The Administration's effort was apparently successful in heightening the sickle-cell awareness of Dr. Alston B. Meade, a senior research biologist at Du Pont, who was also president of the Black Du Pont Employees Association. He became convinced that the company might play a role in helping black employees learn more about sickle-cell anemia. Dr. Meade, who holds a Ph.D. in entomology from the University of Minnesota, tells me that he had no precise scientific reason for so involving his employer. He also says that he did not know very much about either the genetic or the medical characteristics of sickle-cell anemia.

In his asserted lack of knowledge, Dr. Meade was not unique. After months of jawboning, the Government had succeeded in confusing the public about what sickle-cell anemia really is. A great many people, including some in the press, were unable to understand the difference between the actual anemia, which occurs in individuals who carry a gene for it from each parent, and sickle-cell trait, which refers to people who have only one gene for the anemia and may exhibit absolutely no anemic symptoms at all.

4.

It was the difference between homozygosity and heterozygosity, a definition any fair-to-middling high school biology student is able to make. Unfortunately, most people forget what they are taught in high school and Mr. Nixon's desire to find a cure for sickle-cell anemia, however well-meaning, was clearly becoming the source for a lot of misunderstanding and the needless stigmatization of blacks.

Dr. Meade's rather generalized approach was apparent in a letter dated July 8, 1972, which he says he sent both to Du Pont's public relations and employee relations departments:

"Recently there has been much discussion on the deleterious effect of Sickle Cell Anemia on Black families. A significant amount of medical information seems to be accumulating. We ask that the Medical Division be directed to investigate these finds with a view to improving the quality of medical service for Black employees. We are particularly interested in knowing whether Sickle Cell Anemia tests should be given routinely to all Black employees."

5.

All things considered, it seems a curiously naive letter for a Ph.D. in entomology to write, even one who claims, even now, that he does not know very much about genetics and nothing at all about sickle-cell anemia. He says that he alone wrote the letter and I believe him. But I do not understand how a well-educated black man could not have known that it is highly unlikely for any black to reach employment age and not know if he had sickle-cell anemia. This anemia is found in only :2 percent of American blacks but it is quite serious. It is accompanied by jaundice and recurrent attacks of fever and pain in the arms, legs and abdomen from early childhood. It may also be accompanied by severe headaches, paralysis, convulsions and renal damage. A mere carrier simply doesn't have these symptoms. Indeed, most carriers of sickle trait are no more aware that they carry such a gene than is a brown-eyed person aware that he may carry a gene for blue eyes. A test for sickle-cell anemia at the front gate of Du Pont thus seems pointless.

Du Pont says that as a result of Dr. Meade's letter, expressing the wishes of the Black Du Pont Employees Association, a testing program was begun.

6.

It was a pre-employment test given to prospective black employees. At first, it was offered locally, then in all Du Pont plants in the United States. The company says it was and is voluntary, although no black has ever declined to take it. But the test was not for the actual disease of sickle-cell anemia. It was for the heterozygous state of sickle trait, which is carried by eight to 10 percent of American blacks.

I am not suggesting that blacks should not know if they carry a single gene for sickle-cell anemia. But I submit that the only reason for knowing is personal. I have seen no hard data to suggest that the possession of sickle trait makes black workers a liability in American industry, including that part of it that makes chemicals. I would suggest that if anybody is going to say that blacks or people of Mediterranean or Oriental descent are at special risk in the workplace he had better have the facts to prove it.

I am not objecting in any way to the research done with so-called hemolytic chemicals. I am only saying that much more needs to be done before generalizations are made.

In any event, the Du Pont Company began its sickle trait tests.

7.

Du Pont did not contract the sickle tests out to independent physicians who, hopefully, would have had personal and private relationships with each employee tested. Instead, the company elected to do the testing itself. The test results were placed in the workers' medical records, with Du Pont's promise that it was all secret and private.

I should tell you that Du Pont says it has not yet made any effort to derive any systematized data from its sickle trait test program.

But it would seem that the company did not need systematized data, or even unsystematized data, to take sickle trait out of where it should have been -- the personal business of blacks -- and make it into a major concern with workplace.

This is most evident in a May, 1978 article written by Dr. Charles F. Reinhardt of Du Pont for the Journal of Occupational Medicine.

Dr. Reinhardt, director of Du Pont's Haskell Laboratory for Toxicology and Industrial Medicine, wrote that the purpose of the article was to discuss "major aspects of hypersusceptibility involved in occupational medicine and to outline monitoring programs in several key areas."

8.

For the purposes of his article, Dr. Reinhardt used the definition of "hypersusceptibility" as "a condition of inordinate or abnormally increased susceptibility to chemicals, infective agents, or agents which in the normal individual are entirely innocuous."

In a section dealing with sickle-cell anemia, Dr. Reinhardt wrote:

"Several screening tests for sickle-cell trait have now been developed and a number of mass screening programs have been conducted. In Du Pont, as a service, we routinely offer all black employees a test for sickle-cell trait. If the test is positive, we will ask the applicant to check with his or her personal physician or a community health service. At our Chambers Works plant, heterozygotes with a hemoglobin of less than 14 grams per 100 milliliters /of blood/ are restricted from work involving the handling of nitro and amino compounds; if their hemoglobin is greater than 14 grams per 100 milliliters, no restrictions are made. We generally employ individuals with sickle-cell trait who appear otherwise to fill job requirements."

9.

So there it was. A request that had been made out of a feeling that blacks should know if they carried sickle-cell genes had become the focus of a scientific paper on "hypersusceptibility" in the chemical workplace. Something that might have been a factor in family planning had become an employment issue. Blacks at Du Pont had thus become the only ethnic or racial group to be singled out because of alleged special risk on the job.

I was told by a Du Pont official that people with Italian surnames were probably the biggest single group in the Chambers Works plant, which is in Deepwater, N. J. Italians sometimes have sickle-cell anemia, although it is very rare among them, as well as thalassemia and a deficiency of the enzyme glucose-6-phosphate dehydrogenase. Du Pont screened for glucose-6-phosphate dehydrogenase deficiency, but not all the time and in any case, the Italians were not singled out as a special group. Why not?

I called Du Pont's medical director, Dr. Bruce Karrh. He said that no thought had ever been given to testing either for thalassemia trait or the actual disease and that Du Pont had never considered testing white workers of Mediterranean ancestry, as a group, for their genetically linked blood diseases.

10.

Since Dr. Karrh had reviewed Dr. Reinhardt's paper prior to its publication in the Journal of Occupational Medicine, I decided to ask him about the sickle trait test. He offered an entirely different version, saying that no job-placement decisions were based on the tests and that they were "purely for the education and edification of the individual involved." He said the test was designed "only to advise them."

I reported my findings on the Du Pont sickle trait test program last February 4th in The New York Times. It was the second of four articles on genetic screening in American industry.

Du Pont's initial response came on February 5, the day after the company's genetic screening program was reported in The Times. Irving S. Shapiro, the Du Pont chairman, wrote a letter to The Times saying that the sickle trait test was never used in job placement and that my report was "offensive" to a management that "has worked diligently to foster an end to racism in this country." He made no mention of the Reinhardt article, but no matter; The Times printed his letter on February 7.

11.

On February 11, Dr. Meade joined with another Du Pont employee, John C. Fisher, current president of the Black Du Pont Employees Association, to write their own letter to the editor. This letter basically said that the test was requested by the Association and added, "We are not aware of any abuse of the SCA /sickle-cell anemia/ testing program. We welcome any information to the contrary." Like the Shapiro letter, the Fisher-Meade letter made no mention of the Reinhardt article. Since The Times had already reported that blacks had requested the test (although we did not originally know who Dr. Meade was because the company said it discarded its files on the Black Du Pont Employees Association and could not remember the name of the group), the Fisher-Meade letter was not used.

I didn't know anything about the Fisher-Meade letter until February 28, when a rather irritated Dr. Meade called me to inquire why his letter had not been published. Indeed, that conversation was the first inkling I had that there was something called the Black Du Pont Employees Association. Although it was our first conversation, Dr. Meade was forthcoming in his criticism.

12.

So I asked him how he accounted for Dr. Reinhardt's report on the sickle trait test in the Journal of Occupational Medicine.

"I don't know anything about that," Dr. Meade said.

"How could that be?" I responded. "It was right there in The Times article."

"I didn't read The Times article," Dr. Meade said. "I read a version of it in the Philadelphia Bulletin and they made no mention of Dr. Reinhardt."

We rang off, I got hold of the Fisher-Meade letter, and on that very day, I sent tearsheets of my series to Dr. Meade at the address that appeared on the stationery of the Black Du Font Employees Association -- Box 2624, Wilmington, Delaware, 19805. It was returned 10 days later by the Post Office. There was no Black Du Font Employees Association at that address.

In a subsequent telephone call, Dr. Meade explained that the Association's old Post Office box number had expired and that they had not immediately gotten a new Post Office box. This, of course, could happen to anybody, but you will admit, I hope, that not having a receivable address may make it difficult to communicate with any organization.

13.

In any event, Dr. Meade also told me that his association has no formal membership, that it mails a newsletter to only 400 of the company's estimated 11,000 black workers and that it has meetings that usually attract fewer than 10 people.

Please let me emphasize that I am not putting down the Black Du Pont Employees Association or Dr. Meade, but I have reason to believe that it cannot purport to represent the vast majority of black workers at the company since by Dr. Meade's own words, it has nothing to do with those workers.

As it turned out, the edited version of my series that Dr. Meade had read in The Philadelphia Bulletin had, indeed, mentioned the Reinhardt article. And even after I sent another batch of tearsheets of the original Times article to Dr. Meade he would not comment on the Reinhardt statements. He just said he had not had the time to read the tearsheets.

Obviously, when a journalist writes a story that questions the policies of a major company he expects there might be some reaction. But I did not expect the reaction I got from The Washington Post.

14.

On March 10, The Post ran an editorial that was quite supportive of my series.

"The Du Pont screening program illustrates the kind of potential abuse that many believe is inevitable," said The Post, quoting The New York Times as its source. It concluded: "... given the number of potentially dangerous chemicals inside and outside the work place, the right focus for company and government attention is on removing the hazard -- not the people."

It was an unexpected endorsement. I thought it was a little odd that The Washington Post editorial writer had not called me with any questions he or she might have. But the support was nevertheless most welcome.

I didn't have that warm feeling for very long.

Du Pont's public relations department had no intention of taking The Post editorial lying down and sent to the newspaper a letter by the company president, Edward G. Jefferson, and a copy of the original letter written in 1972 by Dr. Meade, along with his more recent missive, penned with John Fisher.

Wonder of wonders, the public relations department scored a major coup.

15.

On March 20, the Post ran a second editorial, apologizing for the first one, noting that the original request for the tests came from blacks (as though I had ignored that fact) and saying: "The program appeared highly questionable because Du Pont did not test members of certain white ethnic groups who carry a related genetic trait at equally high frequency. As it turns out, our sources were wrong. We owe Du Pont an apology, herewith rendered."

As I am sure you understand, it is an extraordinary thing for any newspaper, be it The Fodunk Bugle or The Washington Post, to write an editorial taking one position and then retracting it 16 days later with an apology rendered to the offended company. I have been a journalist for 25 years and I could not conceive that such a retraction would be made by a great newspaper unless a tremendous amount of digging had been done. I will confess to you that I was apprehensive as I dialed The Washington Post's number. The Washington Post had said their sources were wrong and I was their source. How was I wrong?

16.

Meg Greenfield, editor of the editorial page, said that the second editorial ran because Jessica Mathews, one of her editorial writers, became convinced that such a retraction was necessary. She arranged for me to talk to Mrs. Mathews, who had also written the first editorial.

It was the Fisher-Meade letter that did it, said Mrs. Mathews, and, of course, the supporting material from 1972.

I could not believe that Jessica Mathews could have come to the same conclusions if she had spoken to the same Alston Meade I had spoken to, and I was right -- she hadn't spoken to Dr. Meade, not to Mr. Fisher, nor to any members of the Black Du Pont Employees Association. She said she had never even tried to call them and never tried to authenticate anything. Just as bad, she said she made not a single telephone call to Du Pont -- not even to its public relations department -- and had never even bothered to read Dr. Reinhardt's article in The Journal of Occupational Medicine.

17.

As politely as I could under the circumstances, I asked Mrs. Mathews how she could write a retraction without checking any of the source material she had received from the public relations department.

"I am not a reporter," she replied. She hastened to add that she had telephoned three of her own sources, people who had nothing to do with Du Pont or the workers there.

Editorial writing-by-osmosis did not leave Mrs. Mathews bereft of still more opinions, however. She felt that even if Dr. Reinhardt wrote what I reported he wrote (and she was going to check that out right away in a medical library), he probably didn't know anything about company testing policy because, after all, he ran a research facility and research scientists tend not to know very much about medical practices in individual plants.

She did not respond when I informed her that Dr. Reinhardt was formerly employed at Du Pont's Chambers Works plant in Deepwater, N.J., and that he told me he was instrumental in starting a genetic screening program there.

12.

Anyhow, her editorial stands. Du Pont now sends it out, along with the Fisher-Meade letter, when people inquire as to what Du Pont's genetic screening program is all about.

Lewis Milford, a professor at American University, called Du Pont with such an inquiry and says he was told by Matthew T. Cooney, Jr., a Du Pont public relations man, that, "A major paper like The Post doesn't apologize lightly."

As for Dr. Reinhardt's prose as it appears in The Journal of Occupational Medicine, Mr. Cooney says, "This language clearly says that it is a standard hemoglobin test not a sickle test, that is used to restrict a person with a low hemoglobin count from certain areas as a health safeguard."

But the fact is that the language does not say that.

You have heard a portion of Dr. Reinhardt's article in The Journal of Occupational Medicine. If you go back and check the article, you will find that it was not excerpted out of context. Dr. Bruce Karrh, Du Pont's medical director, is rather upset with me. He told me that the Reinhardt article was "a scientific article written for a scientific audience."

19.

It was not written to be dissected word for word to see if you could hang on each little word."

I find that a rather curious appraisal. I had always imagined that scientific papers that have gone through peer review ought to be able to withstand intensive criticism. Some of the other things that Dr. Karrh said are curious to me as well.

Remember, he said that no job placement decisions were made and that the test was "purely for the education and edification of the individual involved."

What education and edification?

Mr. Cooney tells me that the company doesn't even have a uniform, national policy for explaining the sickle trait test to its black employees.

He said that the only time the company notified all black workers what the test was about was in 1972. There has been nothing since then, said Mr. Cooney. He said the policy on informing blacks about the "need" for the sickle trait test is made on a "plantsite by plantsite" basis and Mr. Cooney says he has no idea which blacks are being told and which blacks are not being told.

20.

Little wonder that when a reporter for The Wilmington (Delaware) Morning News interviewed black Du Pont workers about the test, one of them said, "I would venture to say that probably more than 50% of the black employees don't know that this particular test is given."

Education and edification, indeed.

Dr. Karrh has also suggested that when I perceived the inconsistencies between his version of what Du Pont was doing and those of Dr. Reinhardt and Dr. Meade and others, I should have come back to Dr. Karrh so that he could have clarified the issue.

That sort of reporting is called public relations. I am not a PR man for Du Pont; I am a reporter for The New York Times.

In conclusion there are, to say the least, some questions that remain about this sorry business:

(1) Why are blacks alone singled out in the Reinhardt article and why are they the only group being tested for what Dr. Reinhardt calls "chemical hyper-susceptibility," since there are a lot of people of Mediterranean descent working for Du Pont and since some of them may have a trait for thalassemia or be hemizygous for glucose-6-phosphate dehydrogenase deficiency?

21.

Why shouldn't they be tested as a group?

Du Pont does occasionally test for G-6-PD deficiency but has not singled out a racial or ethnic group to do it.

(2) Precisely what is there about the 14 gram hemoglobin level that would suggest that people with it be restricted from certain kinds of work? A number of scientists I interviewed, including Dr. Barton Childs of The Johns Hopkins Medical School, said they could attach no scientific significance to the 14 gram level. If it represents a national standard, I cannot find it in the literature and I would appreciate any clues that members of this audience might be able to provide.

(3) If no blacks have ever been transferred to other jobs because of their sickle trait, how can one explain the statement of William Golt, president of the Chemical Workers Association, a company union, who told me of at least one black who was transferred because of the test?

(4) How and why did The Washington Post write an editorial praising the report in another newspaper and then retract the editorial without checking with any of the principals involved?

22.

And in view of that editorial, how do we explain the comment of its writer, Mrs. Mathews, who rethought the Du Pont situation and told me, "I agree with you. There's something fishy there."

Mrs. Mathews may think there is something fishy there at Du Pont but her editorial apparently remains the pride and joy of Du Pont's public relations department. When I wrote an account of what I have just told you for The Nation, which published it last September 20, The Nation's editor, Victor Navasky, received a letter from Du Pont's Dr. Karrh which said, in part, that "the Washington Post acted responsibly when it reviewed the facts and acknowledged that it was wrong in reprinting the allegations of the Times' article."

And so now we have a company that was not consulted by the newspaper thanking the newspaper for conducting a review that the newspaper admits it did not do.

23.

In closing, let me emphasize that what I have just presented is only a single case study. I like to think that science and journalism generally do better; I cannot believe that they ever did worse. In any event, I'm sure you have questions and I look forward to receiving them.

Thank you.

